

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL :
PRESCRIPTION OPIATE : MDL NO. 2804
LITIGATION :

: CASE NO.
THIS DOCUMENT : 1:17-MD-2804
RELATES TO ALL CASES: Hon. Dan A. Polster

- - -

Friday, April 26, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

- - -

Videotaped deposition of DAVID A.
KESSLER, M.D. (Day 2), taken pursuant to
notice, was held at Baron & Budd, 600 New
Hampshire Avenue NW, Floor G, Washington, DC
20037, beginning at 8:07 a.m., on the above
date, before Lisa V. Feissner, RDR, CRR, Notary
Public.

- - -

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 21 16 Opana ER Kit 489
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 22 17 Letter from Skariah to Best 499
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 23 Reference ID: 3124026
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(It is hereby stipulated and agreed

3

by and among counsel that sealing,

4

filing and certification are waived; and

5

that all objections, except as to the

6

form of the question, will be reserved

7

until the time of trial.)

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9

VIDEO OPERATOR: Today's

10

April 26th. The time is 8:07 a.m., and

11

we are now on the record.

12

This is the continuation of the

13

deposition of David A. Kessler, M.D.,

14

and he has been previously sworn in.

15

You may proceed.

16

MR. DAVIS: Thank you.

17

DAVID A. KESSLER, M.D.,

18

having been previously duly sworn, was examined

19

and testified as follows:

20

EXAMINATION

21

BY MR. DAVIS:

22

Q. Good morning, Dr. Kessler.

23

A. Good morning, sir.

24

Q. My name is Josh Davis. I represent

1 Endo and a number of Endo affiliates, including
2 Par Pharmaceuticals.

3 I'm going to ask you some questions
4 generally and a fair number of questions about
5 Endo specifically.

6 Okay?

7 A. Thank you, sir.

8 Q. You recall yesterday testifying
9 that you're not a mind reader?

10 A. Yes.

11 Q. Do you recall testifying yesterday
12 that you're not going to offer opinions about
13 the intent of authors of particular documents,
14 correct?

15 A. Not about intent.

16 Q. Okay. And is it fair to say that
17 your report with respect to Endo refers to a
18 number of internal Endo documents?

19 A. Yes.

20 Q. And it quotes from those documents;
21 is that right?

22 A. In part, yes.

23 Q. And that includes internal Endo
24 e-mails?

1 A. Yes.

2 Q. And internal Endo marketing
3 strategy documents?

4 A. Correct.

5 Q. And so you're not going to offer an
6 opinion about the intent of the authors of
7 those documents; is that right?

8 A. No. Just anything that's objective
9 evidence, I will base my opinions on.

10 Q. Dr. Kessler, while you were at the
11 FDA, did you communicate in writing with other
12 FDA employees?

13 A. I'm sure.

14 Q. Did you communicate through
15 internal FDA memoranda?

16 A. Can I just give a caveat to that?
17 Most of my interactions, just the technology at
18 the time, was probably verbal is my
19 recollection. I did not do e-mail. It was not
20 my style to write memos or -- I'm not saying
21 there's not things in my handwriting, but
22 there's certainly orders, there's regulations.
23 The things that I wrote tend to be formal
24 documents.

1 Q. Certainly you received memoranda
2 for those who reported to you, correct?

3 A. Of course. You asked me what I
4 wrote. My style was not to write a lot except
5 official documents.

6 Q. You received communications during
7 your time at FDA, correct?

8 A. Of course, sir.

9 Q. And those included written
10 communications?

11 A. Of course, sir.

12 Q. And did that include e-mail, after
13 e-mail was available to you at the FDA?

14 A. You know, you're pushing my memory.

15 Q. Fair.

16 A. It was '97 when I left. I think
17 there may be a little, but it's nothing like it
18 was today, sir.

19 Q. Did you receive internal FDA
20 presentations during your time at FDA?

21 A. Many of those. Not only -- I had
22 presentations -- as they say in Washington,
23 briefings about briefings.

24 Q. Fair. Is it -- and you'd agree

1 that not every internal FDA memoranda that
2 you -- memorandum that you received reflects
3 the final position of FDA, correct?

4 MR. RAFFERTY: Object to the form.

5 A. The memorandum reflects what it
6 reflects.

7 Q. And you would agree that not every
8 memorandum you received at FDA reflects the
9 final position of FDA on the issue described in
10 the memorandum, correct?

11 MR. RAFFERTY: Object to the form.

12 A. If you can clarify what you mean by
13 "final position."

14 Q. Does FDA take final positions on
15 issues?

16 A. FDA -- there's a legal component to
17 that, right, of what is a final agency action.
18 That's why I'm trying to just be careful.
19 That's a legal term because of -- you know,
20 there's a complexity to final agency action and
21 what that means.

22 Q. A single memorandum to you would
23 not reflect FDA's position on an issue,
24 correct?

1 A. Depends on the memorandum. It
2 could or it could not.

3 Q. Well, it would be improper to
4 assume that a single memorandum to you
5 necessarily reflects FDA's final position,
6 correct?

7 A. If it were a memorandum from the
8 President of the United States, it probably may
9 be the final agency action. It depends on the
10 memo, sir.

11 Q. I agree with that.

12 Let's say it's a memorandum from
13 someone several, several layers below you at
14 FDA informing you about a particular issue. It
15 would be improper to assume that a memorandum
16 of that type reflects FDA's final position on
17 that issue, correct?

18 A. Not necessarily.

19 MR. RAFFERTY: Object to the form.

20 A. It depends. Happy to explain.

21 Q. Does every memorandum you received
22 at FDA reflect the final position of FDA?

23 A. Not necessarily, no.

24 Q. That's a no, right?

1 A. Not necessarily.

2 Q. Dr. Kessler, when FDA approves --
3 you're familiar with what a New Drug
4 Application is?

5 A. Yes.

6 Q. And does FDA from time to time
7 approve New Drug Applications?

8 A. Correct.

9 Q. And when FDA approves a New Drug
10 Application, that's based on review of that New
11 Drug Application, correct?

12 A. Correct.

13 Q. And it's based on review of
14 everything in that New Drug Application,
15 correct?

16 A. I wouldn't agree with that
17 statement.

18 Q. FDA -- is it your testimony that
19 FDA approved New Drug Applications without
20 reviewing the complete New Drug Application?

21 A. FDA does not necessarily review
22 every page out of millions and millions of
23 pages. That would be folly if you thought FDA
24 had those resources. I'm happy to explain.

1 Q. There's information -- I just want
2 to make sure your testimony is clear. It's
3 your position that there's information
4 contained in New Drug Applications that FDA
5 ignores?

6 A. I didn't say that.

7 MR. RAFFERTY: Object to the form.

8 Q. Well, you certainly said there's
9 information contained in New Drug Applications
10 that FDA doesn't review, right?

11 A. That's what -- exactly what I said.
12 I didn't say they ignore it.

13 Q. What's the difference between not
14 reviewing and ignoring?

15 A. One is -- one is a -- they're
16 different words, sir. I mean, they imply
17 different things. And I'm happy to explain
18 that, if you'd like. Reviewing -- a
19 reviewer -- let me step back so I can put
20 this -- answer your question more broadly.

21 As you know, when I went to
22 hearings, they would make fun of FDA sometimes,
23 a member of Congress, by just bringing in a New
24 Drug Application to show how vast it is. It

1 would fill this room.

2 The information is available, and
3 when I was there it became electronic, right,
4 so you can search it, right. You have it
5 available.

6 It's not that you -- there's
7 limited resources. So FDA can review things.
8 Doesn't -- does not -- ignore, to your point,
9 has a deliberate component, right. FDA reviews
10 to the best of its resources and its ability
11 and what it thinks is salient. Doesn't
12 deliberately ignore. But no one -- no one
13 thinks that every page is reviewed.

14 Q. Are submissions to FDA of
15 promotional pieces for review as voluminous as
16 New Drug Applications?

17 A. I don't think so. I mean,
18 depending on the size of the NDA. There are
19 short NDAs, and again, what you mean by an NDA.
20 There's a whole range of NDAs. In general, I
21 would not think so.

22 Q. And when FDA reviews a promotional
23 piece, it reviews the entire submission,
24 correct?

1 A. I wish.

2 MR. RAFFERTY: Object to the form.

3 Q. So again, your position is, when
4 FDA receives a submission of a promotional
5 piece -- launch promotional pieces to review,
6 it doesn't review the entire submission?

7 A. It depends on the resources the
8 agency has available, and again, what the
9 reviewer thinks is salient.

10 Q. If FDA had sufficient resources,
11 you would agree that the best course of action
12 would be for FDA to review the entire
13 submission, correct?

14 A. No. I would -- would you like me
15 to explain?

16 Q. The best course -- if resources
17 were not an issue, you don't believe that the
18 best course of action would be for FDA to
19 review the complete submission of a promotional
20 piece?

21 MR. RAFFERTY: Object to the form.

22 A. The agency has to focus -- even if
23 it had endless resources, right, the agency has
24 to focus on the public -- what's important for

1 the public health and what's important for
2 safety. Even if you had umpteen resources,
3 right, you focus on what's -- what you think is
4 important, right. I think that's --

5 Q. Again, I'm taking resources out of
6 the equation, okay? FDA has infinite
7 resources. There's no need to focus. FDA can
8 look at everything.

9 The best course in that situation
10 would be for FDA to review the complete
11 submission, correct?

12 MR. RAFFERTY: Object to the form.

13 A. There aren't enough people -- I
14 mean, there are not enough people, right. Even
15 if you had unlimited dollars, there's not
16 enough talent, right, to be able to focus on
17 everything, just -- I'm having -- trying to
18 comprehend the universe that you're living in
19 or you're trying to -- making a hypothetical.
20 I apologize. I just don't understand that.

21 Q. I'm trying to identify what you
22 believe to be the best-case scenario with
23 respect to -- let's go back to NDAs for a
24 second. I'm trying to identify the best-case

1 scenario in your mind for review of a New Drug
2 Application.

3 You would agree that the best-case
4 scenario, putting resources aside, would be for
5 FDA to review the entire New Drug Application
6 before it approves that NDA, correct?

7 A. I would not make that -- I would
8 not testify to -- in those words in front of
9 Congress. I don't think that would be -- if
10 there's 50 million pages, I don't believe it
11 would -- putting an eyeball against every line
12 of those 50 million pages would be the best
13 scenario. I think that would be folly to be
14 the basis to review 50 million pages.

15 Q. Let me make sure this is clear.

16 As the former FDA Commissioner,
17 your position is that the best-case scenario
18 for FDA would not be to review a complete New
19 Drug Application prior to its approval?

20 A. That's --

21 MR. RAFFERTY: Object to the form.

22 A. That's not what I testified.

23 That's not what I said previously. I'm happy
24 to explain.

1 Q. Well, if you didn't say that your
2 position is that the best-case scenario for FDA
3 would not be to review a complete New Drug
4 Application prior to its approval, that means
5 that the best-case scenario for FDA would be to
6 review a complete New Drug Application prior to
7 its approval.

8 MR. RAFFERTY: Object to the form.

9 Q. It either is or isn't the best-case
10 scenario.

11 MR. RAFFERTY: Object to the form.

12 A. It's certainly -- if you want to
13 make a general statement that -- about
14 complete -- reviewing a complete, sure, but
15 that should not be interpreted as an eyeball
16 against every single line. Just means what you
17 mean by review of complete, sir.

18 Q. Are you familiar with Percocet,
19 Dr. Kessler?

20 A. I am.

21 Q. And Percocet was an approved
22 medication and was on the market when you were
23 the Commissioner at the FDA; is that correct?

24 A. That is correct.

1 Q. And you didn't have any direct
2 personal involvement with Percocet when you
3 were the Commissioner at FDA, correct?

4 A. Not to my knowledge, sir.

5 Q. With respect to Endo, Dr. Kessler,
6 the opinions you're offering in this litigation
7 are limited to two Endo medications, Percocet
8 and Opana ER, correct?

9 A. I think that's correct. I'm just
10 trying to make sure there's nothing on the
11 generic side. But -- so I just have to put an
12 asterisk to double-check that. But I think
13 you're correct.

14 Q. What would you need to do to
15 double-check that?

16 A. I just want to review the report,
17 because there's -- obviously there's the issue
18 of branded generics, and I just would want to
19 review my report.

20 But I think, in essence, you're
21 correct. That's certainly what I'm focused on.

22 Q. If you could at the break confirm
23 that you're correct that the only two Endo
24 products for which you offer an opinion are

1 Percocet and Opana ER, I'd appreciate that.

2 A. Happy to do that, sir.

3 Q. You're not offering any opinions
4 with respect to Par Pharmaceutical, are you,
5 Dr. Kessler?

6 A. So the record can be -- correct.
7 I'm focused on the history -- on drugs.
8 There's a lot of manufacturers. So only to the
9 extent if there's a drug, Percocet or Opana,
10 so -- corporate histories sometimes get
11 complicated, and I may not be fully cognizant
12 of all corporate history, but -- in general.

13 So we can stay to what drugs I'm
14 issuing an opinion on. I'm happy to do that.
15 Corporations become complicated in this current
16 world.

17 Q. Are you familiar with
18 Qualitest Pharmaceuticals?

19 A. Yes.

20 Q. Are you offering any opinions with
21 respect to Qualitest?

22 A. There's nothing, I believe, in my
23 report. But if you ask me questions, I'm happy
24 to discuss it.

1 Q. I'd like to talk with you,
2 Dr. Kessler, about your opinions regarding
3 Endo's promotion of Percocet.

4 A. Yes, sir.

5 Q. Do you have your Exhibit 1 of your
6 report in front of you?

7 A. I have my copy, sir.

8 Q. Your version of your report in
9 front of you?

10 A. Happy to pull it up.

11 Q. And just so the record is clear, I
12 think your report has been marked as Exhibit 1
13 already.

14 A. I'm sure.

15 Q. We can work both off our own copies
16 here, which may be more efficient.

17 A. Thank you.

18 Q. On page 110 of your report --

19 A. Can I just get there, please.

20 Q. Uh-huh.

21 A. Thank you, sir.

22 Q. Specifically paragraphs 191 and
23 192, please.

24 A. Yes.

1 Q. You offer an opinion regarding
2 Endo's marketing strategy for Percocet,
3 correct?

4 A. I'm sorry. I didn't hear your
5 question.

6 Q. You offer an opinion regarding
7 Endo's marketing strategy for Percocet,
8 correct?

9 A. Not -- in those paragraphs? I'm
10 sorry. I'm confused.

11 Q. Do you offer an opinion regarding
12 Endo's marketing strategy for Percocet?

13 A. Yes. I don't think in that
14 paragraph. That's what I'm confused.

15 Q. In paragraphs 191 and 192, you cite
16 to two Endo business and marketing plans,
17 correct?

18 A. Yes, sir.

19 Q. And both of those plans are from
20 the year 2002, correct?

21 THE WITNESS: Gerard, can you do me
22 a favor and just pull the binder for 191
23 and 192, please.

24 Unless you have the documents.

1 Thank you.

2 A. So the second document is dated
3 April 25th, 2002. And I would need to go back
4 and check the metadata on one unless I cite it
5 here on 346. The document I cite in 346, I
6 just have the native, and I don't have a date.
7 I apologize.

8 Q. Doctor, you're about to lose your
9 microphone.

10 A. Thank you, sir.

11 Q. You don't know whether either of
12 those business plans were final business plans,
13 do you?

14 A. I only know the words on the
15 documents as they're stated.

16 Q. Yes or no, you don't know whether
17 those two documents are -- those two business
18 plans are final business plans?

19 A. The documents don't, on the face of
20 them, state one way or the other.

21 Q. So you don't know whether those are
22 final business plans, correct?

23 A. The documents don't state one way
24 or the other.

1 Q. Which means you don't know whether
2 those are final business plans, correct?

3 A. I only know what the documents
4 state.

5 Q. And you've said that the documents
6 don't say whether they're final, which means
7 you don't know whether those are final
8 marketing plans?

9 MR. RAFFERTY: Object to the form,
10 asked and answered.

11 Q. Correct?

12 A. I know what the documents state. I
13 can go back and review them in broader context
14 to get that answer, if you'd like.

15 Q. Well, you just said the documents
16 don't state whether they're final or not, so
17 reviewing them is not going to give you an
18 answer to the question, right? You're not
19 going to know the answer to whether or not
20 those documents are final whether you review
21 them again or not, right?

22 MR. RAFFERTY: Object to the form.

23 A. That's certainly knowable by
24 reviewing a database. I review a lot of

1 business plans, and I -- you can see from
2 context. You can see from versions. There are
3 a lot of ways to determine the answer to your
4 question. I'm happy to do more research to get
5 the answer to your question.

6 Q. You've not done that with respect
7 to those two documents, correct?

8 A. I have read those documents.
9 That's what I've done with regard to those
10 documents.

11 Q. But not sufficiently to know right
12 now whether those are final marketing plans or
13 not, correct?

14 A. I have read those documents to
15 determine -- your question of what's sufficient
16 or not, I'd have to do more research to answer
17 your question.

18 Q. You don't know the answer to my
19 question is what you're saying, right? You
20 don't know whether those are final documents or
21 not?

22 A. I only know what those documents
23 say.

24 MR. RAFFERTY: Object to the form.

1 A. I can't say any more.

2 Q. This will go a bit more efficiently
3 if you can just give me a straight answer to my
4 question. These are not complicated questions.

5 So this is the same problem that we
6 ran into yesterday. It's the same problem that
7 I believe we're all going to face. And it's
8 the same problem that's prejudicing both my
9 client and many of the other co-defendants here
10 today. We're wasting time on answers that are
11 not strictly responsive to the questions that
12 we're asking.

13 I would appreciate it, Dr. Kessler,
14 if you could give me a succinct, responsive
15 answer to my questions going forward. That
16 will make things far more efficient and will
17 lessen the prejudice that my client is
18 experiencing with the time that we have
19 available together and will lessen the
20 prejudice to my co-defendants and my colleagues
21 for the time that they have available. I'd
22 appreciate that.

23 MR. RAFFERTY: What we're wasting
24 time on is giving speeches that are

1 inappropriate under the protocol and
2 that are, quite frankly, incorrect. He
3 has answered succinctly all of your
4 questions so far this morning. So ask
5 your questions, and he will continue to
6 answer them.

7 Q. Dr. Kessler, on page -- actually,
8 you know what, sticking with those two business
9 plans, you don't know whether those business
10 plans were ever presented to anyone, do you?

11 A. I only know what's in these, so
12 obviously right now I'd have to go do more
13 research to see the audience.

14 Q. See, that's a no. If you answer
15 that --

16 MR. RAFFERTY: It's not a no, and
17 you're not going to instruct this
18 witness on how to answer a question,
19 Mr. Davis. It's not going to happen.
20 Ask him the questions.

21 He just said he would have to go
22 get more research. You can take
23 whatever you want. Ask the questions;
24 he'll give you the answer.

1 MR. DAVIS: I'm asking whether he
2 knows it, and when he says, I would have
3 to go do more research, that is a no.
4 That means he doesn't know, Troy.

5 MR. RAFFERTY: No, the answer is
6 whatever the answer is that he gives,
7 Mr. Davis, so --

8 MR. DAVIS: I think you've had this
9 conversation off the record with my
10 co-counsel yesterday. You saw what
11 Special Master Cohen said during the
12 Eagleman deposition about our
13 entitlement to yes or no answers to
14 questions that call for yes or no
15 answers. I'm simply asking that
16 Dr. Kessler provide a yes or no answer
17 to yes or no questions.

18 MR. RAFFERTY: He has given you the
19 answer that you've -- to the questions
20 that you've asked. And I don't know
21 what context was going on with Eagleman,
22 but I can tell you that Dr. Kessler has
23 been answering and been responsive to
24 everybody's questions.

1 MR. DAVIS: Okay. Well, I can tell
2 you if this continues, then we're going
3 to do our best to get Special Master
4 Cohen on the phone to give the same
5 directive that he's given in other
6 contexts.

7 MR. RAFFERTY: I have no problem
8 with that, and I think a clear reading
9 of this record will show that
10 Dr. Kessler has been more than
11 responsive.

12 Q. Dr. Kessler, you don't know to
13 whom, if anyone, those presentations were made,
14 right, the two presentations we've been talking
15 cited in paragraphs -- or referred to in
16 paragraphs 191 and 192 of your report?

17 A. You're correct, those documents
18 don't reflect that.

19 Q. And so you don't know that then?

20 A. I know what -- that's correct. I
21 know what's on these documents.

[illegible]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

13 Q. Who is Ms. Kitlinski?

14 A. Just give me one second. I'd have
15 to go back and double-check exactly her title.

16 Q. As you sit here today, you don't
17 know who Ms. Kitlinski is, right?

18 A. I -- I'd have to go back and
19 review. I don't -- I don't have it at the top
20 of my head. I don't have it -- let me -- let
21 me just double-check that. Hold on one second.

22 Q. What are you using to double-check
23 who Ms. Kitlinski is?

24 A. I just want to check my report for

1 a second, please.

2 Q. Is Ms. Kitlinski -- was
3 Ms. Kitlinski in 1998 the CEO of Endo?

4 A. I don't have that in my -- I don't
5 have that in my head right now.

6 Q. Was Ms. Kitlinski the chairman of
7 the board of directors of Endo at that -- in
8 1998?

9 A. I don't believe so, but I -- again,
10 let me see if I can --

11 Q. Was Ms. Kitlinski the president of
12 Endo in 1998?

13 A. I don't believe so, but again, I
14 don't -- let me just see if I have -- I have a
15 chart of all titles, and I'm just -- just give
16 me a second, if I can see if I can find it.
17 Just give me one more second, please.

18 I don't have the -- actually, I
19 have the deposition. I can find it. But I
20 don't --

21 Q. Do you know whether Ms. Kitlinski
22 was deposed?

23 A. Yes.

24 Q. Did you read the entirety of her

1 deposition transcript?

2 A. No, I did not. I searched -- it
3 was part of my search.

[illegible]

☐ ☐

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99	100%	100%
100	100%	100%

23 Q. You don't know?

24 A. I only know what this document

1 reflects as far as goals and objectives, and
2 she was an Endo employee.

3 Q. Okay. And again, you're not
4 offering any -- any opinion as to what
5 Ms. Kitlinski actually meant by any of the
6 words in this document, correct?

7 A. The words speak for themselves.
8 I'm not -- I'm not going beyond the words, sir.

9 Q. You don't know whether
10 Ms. Kitlinski's goals and objectives extended
11 beyond this -- the middle of 1998, correct?

12 MR. RAFFERTY: Object to the form.

13 A. I only -- that would be fair.
14 There would be mid-year goals. Goals usually
15 reflect a period of time.

16 Q. And this period of time is the
17 middle of 1998, right?

18 A. That's fair.

19 Q. Okay. Dr. Kessler, you're -- you
20 understand that there -- do you understand
21 there's a difference between promotional and
22 non-promotional education?

23 A. I think I can --

24 Q. Strike that. Dr. Kessler, in

1 paragraph 194.2 --

2 A. Let me get there, please.

3 Q. -- you again -- in support of your
4 opinion that Endo's promotional plans for
5 Percocet included using medical education to
6 market Percocet, you generally cite 1998
7 objectives from Ms. Kessler -- from
8 Ms. Kitlinski? I apologize.

9 A. In 194.2?

10 Q. That's right. Just so you have it
11 in front of you, I show you what's been marked
12 as Kessler 13.

13 (Exhibit Kessler-13 marked for
14 identification and attached to the
15 transcript.)

16 BY MR. DAVIS:

17 Q. This is the document cited in
18 paragraph 194.2.

19 MR. RAFFERTY: Mr. Davis, I think
20 you just misspoke. You said 1998.

21 MR. DAVIS: Oh, I'm sorry, 19- --

22 MR. RAFFERTY: I think you mean
23 1999.

24 MR. DAVIS: That's right, thank

1 you. 1999.

2 Q. And again, these are
3 Ms. Kitlinski's objectives for 1999, right?

4 MR. RAFFERTY: Object to the form.

5 A. Yes.

6 Q. Okay. You don't know whether she
7 achieved any of these objectives, do you?

8 A. I only know these are the
9 objectives, sir.

10 Q. Okay. You don't know whether these
11 objectives are the same as Endo's corporate
12 objectives, correct?

13 A. Give me a second, if I can just
14 review this for a second.

15 These would appear to be consistent
16 with the corporate goals.

17 Q. What's the basis of your opinion
18 that these are consistent with the corporate
19 goals?

20 A. I've seen, for example, statements
21 by -- and I have to match up dates -- but, for
22 example, Carol Ammon talking about the
23 corporate strategy of Endo, has said publicly
24 that getting physicians to be acquainted with

1 our products, but more importantly, it's
2 getting physicians who are thought leaders that
3 would not only talk about our products, but
4 would really start to move the whole market
5 towards a change in pain management. That was
6 articulated as one of the major corporate goals
7 and strategies by I believe the CEO at the
8 time.

9 And certainly in a number of the
10 bullets that I am reviewing on this document,
11 these seem to match up. I'm happy to go into
12 more detail about some of these bullets if
13 you'd like.

14 Q. What are you reading from there,
15 Dr. Kessler?

16 A. That is a transcript of a public
17 statement by Ms. Ammon.

18 Q. Is that part of your reliance
19 materials?

20 A. I'm sure -- I'm sure that is in my
21 report at some point. It's publicly available
22 on YouTube. You can go watch it.

23 Q. And that whole sheet that you're
24 looking at, what is that? Did you prepare that

1 yourself?

2 A. Yes. This is mine. I did ask
3 someone to type -- to sit there in front of the
4 YouTube as I was listening to the -- to the
5 video, so that I didn't type that. This is
6 your document. This is all my handwriting.

7 MR. DAVIS: I believe this request
8 was made yesterday. But to the extent
9 that Dr. Kessler is going to be relying
10 on documents in front of him during the
11 course of his testimony, I think it's
12 improper for him to do that without
13 those documents having been provided to
14 us.

15 MR. RAFFERTY: I believe they're
16 all on -- they're all on the reliance
17 list.

18 MR. DAVIS: His handwriting is all
19 on the reliance list?

20 MR. RAFFERTY: You can get his
21 notes, but there's nothing wrong with
22 him making notes and relying upon it.
23 You can get copies of them.

24 MR. DAVIS: That's my request, and

1 I think it was made yesterday. I think
2 it's improper for us not to have them in
3 advance of the deposition.

4 MR. RAFFERTY: Well, I disagree.
5 He can make whatever notes he wants and
6 bring them in, and you're entitled to
7 have them, but there's no rule that says
8 you can get them, you know, days in
9 advance, his notes, I mean --

10 MR. DAVIS: Well, we can take up
11 that discussion later on. But I'll
12 renew the request that we get copies of
13 the notes that Dr. Kessler is relying on
14 during the course of his testimony.

15 MR. RAFFERTY: You're more than
16 welcome to.

17 MS. FREIWALD: May we --

18 MR. DAVIS: I think the request is,
19 correct me if I'm wrong, that we
20 actually mark these notes as an exhibit.
21 I think we've got a sticker here that we
22 can use to do that. So we can mark at
23 least these right now as Kessler-14.

24 THE WITNESS: Tell me where you'd

1 like me to put it this.

2 MR. DAVIS: You can put it on a
3 place that's not going to obstruct
4 that --

5 THE WITNESS: Thank you, sir.

6 MR. RAFFERTY: You should put it on
7 whatever the front page is. Oh, there
8 it is. Okay.

9 (Reporter interruption.)

10 (Exhibit Kessler-14 marked for
11 identification and attached to the
12 transcript.)

13 MS. FREIWALD: Get the whole stack.

14 MR. DAVIS: That's the Endo stack.
15 I think maybe when we go on a break, we
16 can sort of figure out marking the whole
17 and we can introduce them in the next
18 one.

19 MS. FREIWALD: Yes.

20 BY MR. DAVIS:

21 Q. All right. So Ms. Ammon's -- the
22 testimony for -- or the commentary from
23 Ms. Ammon that you just read doesn't include
24 every single bullet point here in

1 Ms. Kitlinski's 1999 objectives, correct?

2 A. She doesn't --

3 Q. Right?

4 A. Well --

5 Q. It's a really easy yes or no.

6 A. Give me a second. Let me read
7 every bullet point and then answer your
8 question.

9 Q. Dr. Kessler, look at the quote on
10 the page from Carol Ammon. Does that look
11 anything like all of the bullet points in the
12 exhibit that you're filibustering and reading
13 right now?

14 MR. RAFFERTY: There's no
15 filibustering. You asked him about
16 whether or not the quote is contained in
17 it. It certainly could be contained as
18 a summary in it. It could be -- he's
19 got a right to read the document you're
20 asking him about.

21 A. Let me tell you the question --
22 what I need to determine. I need to know
23 whether all these -- every bullet here is
24 encompassed by Ms. Ammon's -- that's what I

1 would look to to determine --

2 Q. That's not my question,
3 Dr. Kessler.

4 MR. RAFFERTY: That was your
5 question.

6 MR. DAVIS: It was not my question.

7 Q. Is every single bullet point in
8 Ms. Kitlinski's 1999 objectives included -- the
9 bullet points included in the quote you read
10 from Ms. Ammon?

11 A. Is it encompassed -- when you say
12 "included," I'm sorry --

13 Q. I said "included," "specifically
14 included." Not "encompassed" but "specifically
15 included."

16 A. The concept?

17 Q. No, the specific bullet points.
18 Are these specific bullet points --

19 A. The exact words?

20 Q. Yes. The specific bullet points,
21 are they in that quote from Ms. Ammon?

22 A. These words are not the exact
23 same --

24 Q. Thank you.

1 A. -- as Ms. Ammon's.

2 MR. WEINBERGER: There's no reason
3 to get upset. Everybody can be civil.

4 MR. DAVIS: Pete, enough. Why are
5 you here?

6 MR. WEINBERGER: Why am I here?

7 MR. RAFFERTY: Wow, are you kidding
8 me?

9 MS. AMINOLROAYA: Getting
10 (inaudible), Josh. Can't control
11 yourself.

12 THE WITNESS: Do me a favor,
13 please. When counsel is -- call me back
14 in the room when people are not --

15 MR. DAVIS: We can go off the
16 record if there's any discussion you
17 want to have.

18 THE WITNESS: Please have this off
19 the record.

20 VIDEO OPERATOR: 8:45, we are off
21 the video record.

22 (Recess from 8:45 a.m. until
23 8:52 a.m.)

24 VIDEO OPERATOR: 8:52, we are on

1 the video record.

2 BY MR. DAVIS:

█ █ [REDACTED]

█ [REDACTED]

█ [REDACTED]

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█ [REDACTED]

[illegible]

[illegible]

■ [REDACTED]

2 A. Can you give me a copy? That would
3 be great.

4 Q. It's on your report.

5 THE WITNESS: Gerard, can I have my
6 book?

7 Q. I'm not going to ask you about the
8 substance of the piece --

9 A. Okay.

10 Q. -- Dr. Kessler.

11 A. Thank you.

12 Q. So you don't know, Dr. Kessler,
13 whether this promotional piece was -- you don't
14 have any evidence that this promotional piece
15 was shown to any prescriber in Cuyahoga or
16 Summit County, Ohio, correct?

17 A. Sitting here today, I don't -- I
18 don't know the -- the -- it's 200.3? I just
19 want to see the piece, if I may.

20 Q. What is looking at the piece,
21 Dr. Kessler, going to tell you about whether it
22 was shown to any doctor in Cuyahoga or Summit
23 County?

24 A. There's certain piece --

1 MR. RAFFERTY: He's entitled to
2 look at the document.

3 MR. DAVIS: I just asked him a
4 question.

5 MR. RAFFERTY: I'm objecting
6 because the witness is entitled to look
7 at a document you're asking him about.

8 Q. What is looking at the promotional
9 piece -- again, Dr. Kessler, what is looking at
10 the promotional piece going to tell you about
11 whether it was shown to any doctor in Cuyahoga
12 or Summit County?

13 A. I'm interested whether it was a
14 homemade piece or whether it was a national
15 piece, and that could affect my appraisal of
16 that answer.

Row	Start (approx. %)	End (approx. %)
1	25	85
2	10	78
3	25	100
4	10	98
5	10	95
6	10	98
7	10	45
8	25	98

A horizontal bar chart with 20 rows of data. Each row starts with a small square marker. The bars represent percentages of respondents. The data is as follows:

Category	Percentage (%)
Category 1	95
Category 2	88
Category 3	25
Category 4	92
Category 5	83
Category 6	90
Category 7	95
Category 8	98
Category 9	80
Category 10	92
Category 11	88
Category 12	95
Category 13	85
Category 14	98
Category 15	82
Category 16	95
Category 17	88
Category 18	92
Category 19	98
Category 20	85

[illegible]

[illegible]

[illegible]

[illegible]

■ [REDACTED]

2 Q. And again, you're aware that
3 Opana ER was approved in 2006, correct?

4 A. That's correct.

5 Q. So at least this portion of your
6 opinion regarding Endo's marketing strategy for
7 Opana ER is based upon documents created four
8 years before the launch of the product?

9 A. Let me just check.

10 These -- that's correct with regard
11 to these -- with regard to these paragraphs.

12 Q. Okay.

13 A. And Ms. Kitlinski's title is on
14 216.2. I just didn't remember it.

15 Q. Again, there you cite e-mail
16 correspondence from Ms. Kitlinski from 2003,
17 correct?

18 A. That's exactly correct.

19 Q. And additional correspondence
20 from -- in paragraph 216.5, correspondence from
21 Vin Tormo from 2003, correct?

22 A. That's exactly what I cite.

23 Q. And those e-mails were three
24 years -- dated three years prior to the launch

1 of Opana ER, correct?

2 A. That's exactly when these e-mails
3 are dated.

4 Q. So at least this portion of your
5 opinion --

6 A. Hold on a second. My microphone
7 disappeared. I apologize. Sorry. I
8 apologize.

■ ■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

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■ ■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

[illegible]

1 Q. You've not reviewed all of the
2 correspondence with FDA regarding the removal
3 of Numorphan from the market, have you?

4 A. I've read some of the history of
5 it. I wouldn't want to represent that I've
6 looked at everything. I'm not sure the record
7 has everything.

8 Q. You weren't at the FDA when
9 Numorphan was withdrawn from the market,
10 correct?

11 A. I don't believe so.

12 Q. You can't speak to the specific
13 circumstances regarding the withdrawal of
14 Numorphan from the market, can you?

15 A. Did you say -- sure. There was
16 very significant concerns about abuse. I'm not
17 sure I'm missing -- this was a very highly
18 potent product that was being extensively
19 abused. One of the most potent compounds known
20 to man.

■ ■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ ■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12 Q. Is your knowledge about the
13 withdrawal of Numorphan based on anything not
14 cited in your report or your reliance
15 materials?

16 A. Maybe my general knowledge -- my
17 general education.

18 Q. You're aware, Dr. Kessler, that
19 since its launch in 2006, Opana ER has
20 always -- the label for Opana ER has always
21 contained a black box warning?

22 A. I believe so, yes, of course.

23 Q. And the black box warning indicated
24 that Opana ER contained oxymorphone?

1 A. If you can show me the black box
2 warning. But of course, it -- I mean, I'm
3 sure -- I just want to make sure what's in the
4 black box warning as opposed to what's next to
5 the black box warning. But I'm pretty sure
6 that's correct.

7 Q. Dr. Kessler, I realize the label
8 for Opana, like other opioid products, has
9 changed over time.

10 (Exhibit Kessler-15 marked for
11 identification and attached to the
12 transcript.)

13 BY MR. DAVIS:

14 Q. I'm showing you what's been marked
15 Kessler-15. This is the Opana ER -- this is
16 the Opana ER label from 2009.

17 A. Thank you, sir.

18 Q. And you can see there that the
19 black box warning reads, Opana ER contains
20 oxymorphone, correct?

21 A. That's exactly what it says.

22 Q. With an abuse liability similar to
23 other opioid analgesics, correct?

24 A. Correct.

1 Q. Oxymorphone can be abused in a
2 manner similar to other opioid agonists,
3 correct?

4 A. You read it correctly.

5 Q. Legal or illicit, correct?

6 A. Correct.

7 Q. You're aware that all of Endo's
8 promotional materials for Opana ER contain the
9 black box warning, correct, for Opana ER?

10 MR. RAFFERTY: Object to the form.

11 A. I don't -- I don't -- depend on how
12 you define "materials."

13 Q. You've not reviewed every single
14 Opana ER promotional piece, have you?

15 A. No. I don't think any -- no. I
16 don't think -- I think that would be a fair
17 statement.

18 Q. In fact, you cite five Opana ER
19 promotional pieces in your report, correct?

20 A. I'd have to go back and check. I
21 don't know -- I haven't counted it up.

22 Q. I can represent to you that there
23 are five Opana ER promotional pieces cited in
24 your report.

The diagram consists of a vertical list of 15 items on the left, each represented by a small square. To the right of each item is a horizontal bar of varying length, representing a level of completion or progress. The bars are arranged in a staggered fashion, with some starting further to the right than others. The lengths of the bars vary significantly, with some being very short and others being nearly as long as the list itself.

18 Q. And doctors' perceptions can be
19 based on any number of things, correct?

20 A. Yeah, I'm not sure that's exactly
21 correct. I mean, they certainly can be
22 affected by a number of things.

23 Q. Doctors get information from places
24 other than pharmaceutical promotional

1 marketing, correct?

2 MR. RAFFERTY: Object to the form.

3 A. They can.

4 Q. And they do?

5 MR. RAFFERTY: Object to the form.

6 A. Depends. We don't know in any
7 specific instance. You'd have to be more
8 specific.

The diagram consists of a vertical column of 15 small black squares on the left side. To the right of each square is a horizontal black bar. The bars vary in their starting and ending horizontal positions relative to the squares. Some bars start at the same horizontal position as their corresponding square, while others are indented. The bars also vary in length, with some extending almost the full width of the image and others being much shorter.

A series of 20 horizontal bars of varying lengths and positions, representing a data visualization. The bars are arranged in a list-like structure, with some bars starting at the left margin and others indented. The lengths of the bars vary significantly, with some spanning most of the width of the image and others being much shorter. The bars are solid black and are set against a white background.

20 Q. FDA doesn't provide comment on
21 every single piece it reviews, correct?

22 A. Your point is exactly -- in fact,
23 what you see is, there's umpteen things that
24 are sent in. FDA doesn't have the resources.

1 In fact, at this time, there were very limited
2 resources, and there are only a handful of
3 reviewers. So that's impossible.

The image is entirely black and contains no visible content.

20 Q. Were you the head of DDMAC during
21 your time as head of FDA, Dr. Kessler?

22 MR. RAFFERTY: Object to the form.

23 This was all gone over.

24 You can answer.

1 A. DDMAC reported to me.

2 Q. You weren't the head of DDMAC
3 during your time at FDA, correct?

4 MR. RAFFERTY: Object to the form.

5 A. It reported to me. Depends what
6 you mean by "head." It had its director. That
7 director reported to me. And I was intimately
8 involved with that division.

9 Q. Your title was never director of
10 DDMAC, was it?

11 A. I was Commissioner of FDA.

12 Q. Page 135 of your report,
13 paragraph 224.2, you refer to --

14 A. I'm sorry. 224.2?

15 Q. 224.2.

16 A. Yes.

17 Q. Dr. Kessler, you testified that FDA
18 did not send a warning letter because it lacked
19 resources, correct?

20 A. I think I testified that it did not
21 send a warning letter, period. It lacked
22 resources, period.

23 And certainly on coupons, you
24 shouldn't downplay the risk of addiction,

1 period.

2 Q. So you don't know exactly why FDA
3 didn't send a warning letter with respect to
4 that piece or any piece?

5 And when I say "that piece," I mean
6 the promotional piece marked Kessler-16.

7 A. We don't have a record to answer
8 your question.

9 Q. Okay. So anything you say is just
10 a guess about whether a warning letter -- why a
11 warning letter was not sent, correct?

12 MR. RAFFERTY: Object to the form.

13 A. No. It's based on my experience,
14 and I've been there, and I know the resources,
15 and I know the reality.

16 Q. But specifically, you don't know
17 why FDA did not send a warning letter with
18 respect to any particular piece, correct?

19 MR. RAFFERTY: Object to the form,
20 asked and answered.

21 A. Again, the record, I think, doesn't
22 reflect that with regard to this piece.

23 Q. Or any particular piece that I've
24 put in front of you regarding Opana ER or

1 Percocet, correct?

2 A. I don't think we have the internal
3 FDA record here.

4 Q. So you don't know exactly why FDA
5 did not send a warning letter or untitled
6 letter regarding any of those pieces I've put
7 in front of you?

8 MR. RAFFERTY: Object to the form,
9 asked and answered.

10 Q. The answer is?

11 A. I believe I answered that question.

12 Q. When? Let me ask it again just so
13 the record is clear, because I got an objection
14 and no answer.

15 So you don't know exactly why FDA
16 did not send a warning letter or untitled
17 letter regarding any of the Opana or Percocet
18 pieces I've put in front of you?

19 A. I don't know exactly why in this
20 instance.

21 Q. Thank you.

22 A. But -- I don't know exactly why in
23 this instance.

24 MR. RAFFERTY: Are you done?

■ ■ [REDACTED]

■ [REDACTED]

■ [REDACTED]

■ ■ [REDACTED]

■ ■ [REDACTED]

■ [REDACTED]

■ ■ [REDACTED] [REDACTED]

■ [REDACTED]

9 Q. And again, you're not aware of Endo
10 ever receiving any untitled letter or -- strike
11 that.

12 I want to talk a little bit,
13 Dr. Kessler, about the promotion of
14 reformulated Opana ER.

15 Are you familiar with reformulated
16 Opana ER?

17 A. I do. I am familiar. Let me just
18 get it.

19 Q. And in particular, in --

20 MR. RAFFERTY: I'm sorry. Are you
21 done with this?

22 MR. DAVIS: Yes.

23 Q. Paragraph 159 -- I'm sorry.
24 Paragraph 257 on page 159 of your report,

1 Dr. Kessler.

2 A. Paragraph 257?

3 Q. Yes.

4 THE WITNESS: Gerard, please.

5 A. Yes, sir.

█ █ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ █ [REDACTED]

█ █ [REDACTED]

█ [REDACTED]

█ [REDACTED]

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█ █ [REDACTED]

█ [REDACTED]

█ █ [REDACTED]

█ █ [REDACTED]

█ [REDACTED]

A horizontal bar chart with 20 rows. Each row consists of a small square marker on the left, followed by a text label, and then a horizontal bar representing a percentage. The bars are black and extend to the right. The categories and their approximate percentages are as follows:

Category	Percentage
1. Very high	15%
2. High	45%
3. Medium	55%
4. Low	25%
5. Very low	10%
6. Not applicable	5%
7. Other	40%
8. Very high	55%
9. High	95%
10. Medium	85%
11. Low	90%
12. Very low	10%
13. Not applicable	5%
14. Other	85%
15. Very high	85%
16. High	80%
17. Medium	10%
18. Low	5%
19. Very low	5%
20. Not applicable	95%

1 Q. Are you familiar with Dr. Hertz?

2 A. Sure. I'm not sure I know her,
3 but --

4 Q. Who is Dr. Hertz?

5 A. Sharon Hertz.

6 Q. And was she employed by the FDA at
7 any point?

8 A. Yes.

9 Q. Do you know what her role at FDA
10 was?

11 A. She was, I believe, division
12 director at one point.

13 Q. Okay. And are you aware of
14 Dr. Hertz offering commentary on the
15 appropriateness of promotional comments
16 regarding the design or the intent of an
17 abuse-deterrent product?

18 A. I'd have to --

19 MR. RAFFERTY: Object to the form.

20 A. I'd have to review her entire
21 record or comments.

22 MR. DAVIS: So I'm going to mark
23 here as Exhibit 18 Endo's submission of
24 its reformulated Opana ER promotional

1 materials.

2 (Exhibit Kessler-18 marked for
3 identification and attached to the
4 transcript.)

5 BY MR. DAVIS:

6 Q. This is just an excerpt. We have
7 the complete -- oh, I'm sorry, Dr. Kessler.

8 A. Thank you.

9 Q. I have the complete submission, if
10 you think it would be helpful just for context,
11 but it's massive.

12 A. Yeah, no, this is -- I appreciate
13 that. Just give me one second, if I can. Let
14 me just get oriented for a second. Just give
15 me a second.

16 Sir, you handed me Kessler-18.

17 Q. Yes. And I want to point you --

█ [REDACTED]

█ [REDACTED] [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED]

█ [REDACTED] [REDACTED]

█ [REDACTED]

[illegible]

[illegible]

■ [REDACTED]

■ [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED] [REDACTED]

■ [REDACTED]

6 Q. Okay. You can set that aside.

7 A. Can I just give -- I've taken this
8 out of order. I apologize. Can I give you
9 this?

10 Q. We can fix that.

11 A. I apologize.

12 Q. That's no problem.

13 Dr. Kessler, your report cites to a
14 number of third-party materials ostensibly
15 funded by Endo, correct?

16 A. We can -- I'm not sure the word
17 "ostensibly." We have the funding. We know
18 funding. So those are -- so without that word,
19 yes.

20 Q. Do you know -- did you review any
21 of the grant agreements by which Endo provided
22 the funding you describe in your report?

23 A. I may have. I'd have to go back
24 and review specifically.

1 Q. If you had, would it have been in
2 your reliance materials?

3 A. If I relied on it -- I'm looking at
4 a lot of documents on the computer, so I don't
5 want to say the reliance looks at every
6 document that I looked at on the computer.
7 That's impossible.

8 But I was certainly searching for
9 and went through the NIPC, for example,
10 documents on the computer. But the reliance
11 list should have the things that I'm relying
12 on.

13 Q. You're familiar with the
14 Accreditation Council for Continuing Medical
15 Education, ACCME?

16 A. Intimately, and happy to discuss
17 it.

18 Q. And you're familiar with the ACCME
19 guidelines?

20 A. And which ones? What date? Which
21 ones?

22 Q. 2002.

23 A. If you want to give me them -- I
24 would appreciate if you'd give me those.

1 Q. Can we talk about them at a general
2 level?

3 A. Sure.

4 Q. Would you agree -- when you said
5 you're intimately familiar with the ACCME --

6 A. But I'm not familiar with --
7 there's different versions, and there's
8 different points in time in the history of
9 ACCME.

10 Q. Are you aware of any point from
11 1998 on that the ACCME guidelines controlled --
12 permitted a donor to control the content of
13 continuing -- independent continuing medical
14 education?

15 A. It's complicated.

16 Q. Are you aware of any point in time
17 since 1998 where the ACCME guidelines permitted
18 the donor to have control over the content of
19 continuing medical education?

20 A. Again, I think it's a complicated
21 answer to that question.

22 I think those guidelines, certainly
23 as interpreted -- as pharma did them, there
24 were different extensive control that -- again,

1 we can discuss whether they violated the policy
2 or not. There's a lot of ways to exert
3 control.

4 Q. Your report refers to NIPC?

5 A. Yes.

6 Q. Okay. Are you aware of NIPC ever
7 losing ACCME accreditation?

8 A. Sitting here today, I am not, top
9 of my head. I don't give that any credence,
10 though.

11 Q. Your report also refers to the
12 American Pain Society, APS, correct?

13 A. Yes.

14 Q. Are you aware of APS ever losing
15 its ACCME accreditation?

16 A. I'm not. But again, I don't give
17 that any credence.

18 Q. Your report refers to AAPM. You're
19 familiar with that organization?

20 A. Yes.

21 Q. That's the American Academy of Pain
22 Management; is that right?

23 A. Yes, sir.

24 Q. Okay. Were you ever aware of AAPM

1 ever losing its ACCME accreditation?

2 A. Same answer. I'm not, as I sit
3 here. But again, I don't give it any credence.

4 Q. Are you familiar with the American
5 Pain Foundation?

6 A. Yes.

7 Q. And you refer to that in your
8 report?

9 A. I do.

10 Q. Are you aware of APF, the American
11 Pain Foundation, ever losing its ACCME
12 accreditation?

13 A. It certainly should have.

14 Q. Did it?

15 A. I'd have to go back and review the
16 record.

17 Q. You're not aware of it ever
18 losing --

19 A. Correct.

20 Q. -- its ACCME --

21 A. Correct.

22 It certainly should have. I think
23 there's no question about that.

24 Q. I just want to make sure I get this

1 question in before the answer.

2 You're not aware of APF ever losing
3 its ACCME accreditation, correct?

4 A. That's correct, as I -- as I sit
5 here today, without further research.

6 Q. Dr. Kessler, I think you testified
7 yesterday that you're not here as an expert in
8 DEA regulations. Is that right?

9 MR. RAFFERTY: Object to the form.

10 A. The Court can determine what I have
11 expertise on, or others can determine what I
12 have expertise.

13 I probably have, you know --
14 certainly, as -- as it relates to DEA/FDA
15 interactions, I probably have a good deal of
16 expertise in that, and probably more so than
17 almost anyone, when comes to FDA/DEA. I
18 certainly have it.

19 I think it's fair to say -- I
20 certainly hope that others will testify about
21 DEA. I can help the Court, I mean, on things
22 that I do have expertise that relates to
23 controlled substances and the national
24 strategy, including DEA.

1 Q. Which doesn't include suspicious
2 order monitoring?

3 A. Well, there is suspicious order
4 monitoring of manufacturers, sir, that applies
5 to the manufacturers, and I think I'll leave
6 that primarily to others.

7 I certainly wouldn't talk to
8 distributors, but I'm happy to discuss a little
9 with regard to the manufacturers.

10 Q. You're not an epidemiologist, are
11 you, Dr. Kessler?

12 A. I'm a professor of epidemiology.

13 Q. Dr. Kessler, yesterday -- and I
14 don't want to get into the specifics, but
15 yesterday, you referred to two instances where
16 companies with whom you were affiliated
17 addressed things that, I think as you described
18 it, were out of regulatory compliance.

19 Do you recall that testimony?

20 A. Or potentially, yes.

21 Q. And you cited to two particular
22 instances, correct? Do you recall that?

23 Again, I don't need -- I'm not
24 going to ask you about the specifics, but do

1 you recall?

2 A. Yes, I do.

3 Q. And you testified that you worked
4 with the company to work through those issues,
5 correct?

6 A. Yes.

7 Q. Okay. And you did so at the board
8 level; is that right?

9 A. Yes.

10 Q. Okay. One of the issues --
11 compliance issues that you worked through was
12 identified externally.

13 Do you recall that?

14 A. One had an external component.

15 Q. Fair.

16 And the other was identified
17 internally, correct?

18 A. Correct.

19 MR. RAFFERTY: Objection. This has
20 all been gone over and asked and
21 answered.

22 Q. And you would agree that it was
23 important for those companies to work through
24 those compliance issues, correct?

1 A. Of course.

2 Q. And to address those compliance
3 issues, correct?

4 A. Of course.

5 Q. And would that apply equally to any
6 regulatory compliance issue you, yourself, had
7 identified for those companies? Correct?

8 A. Sure. Individual board members --
9 I'm not sitting there identifying individual
10 issues; I'm at a board level. So it's a little
11 more complicated than -- you know.

12 I don't want to give you a sense
13 that I'm working as -- I mean, these are --
14 this is privately held -- you're familiar with
15 that -- and I'm on a board. This is at a board
16 level.

17 Q. Fair, Dr. Kessler.

18 I'm not suggesting that in your
19 role as a board member, you have a
20 responsibility to monitor, but --

21 A. There is some monitoring, but I
22 just want to give -- there's a board role, and
23 there's a -- regulatory operations, and those
24 are different. That was my only point.

1 Q. In your role as a board member --

2 A. Yes.

3 Q. -- if you become aware of a
4 regulatory compliance issue, you would agree,
5 Dr. Kessler, that it's important for that issue
6 to be addressed, correct?

7 A. Absolutely.

8 Q. Okay. Including at the board
9 level, right?

10 A. I wouldn't say, if I became aware
11 of an issue, that I would bring it necessarily
12 to the full board. I may bring it to the
13 compliance committee. I may bring it to the
14 director of regulatory affairs. It depends on
15 the seriousness of the matter.

16 MR. DAVIS: Can we take a
17 five-minute break? I've got limited
18 time. I just want to organize it.
19 Really, five minutes, if that's okay.

20 MR. RAFFERTY: Sure.

21 VIDEO OPERATOR: 9:43, we are off
22 the video record.

23 (Recess from 9:43 a.m. until
24 9:57 a.m.)

1 VIDEO OPERATOR: 9:57. We are on
2 video record.

3 BY MR. DAVIS:

4 Q. Dr. Kessler, page 121 of your
5 report --

6 A. Give me a second, please.

7 Q. Sure.

8 -- heading number 4 --

9 A. Yes.

The diagram illustrates a sequence of 15 steps in a process flow. Each step is represented by a small square icon followed by a text label. The steps are arranged in a vertical column, with some steps having additional text or icons to the right, indicating a complex flow.

1. [Icon] [Text]
2. [Icon] [Text]
3. [Icon] [Text]
4. [Icon] [Text]
5. [Icon] [Text]
6. [Icon] [Text]
7. [Icon] [Text]
8. [Icon] [Text]
9. [Icon] [Text]
10. [Icon] [Text]
11. [Icon] [Text]
12. [Icon] [Text]
13. [Icon] [Text]
14. [Icon] [Text]
15. [Icon] [Text]

[illegible]

■ [REDACTED]

■ [REDACTED]

3 Q. Is that your complete methodology
4 for determining -- for your opinion that Endo's
5 promotion led to an increase in reports of
6 Percocet abuse?

7 MR. RAFFERTY: Object to the form.

8 A. I won't use the word -- that's the
9 general logic train. It is pretty simple when
10 you study it, but there's obviously -- if you
11 look -- we can discuss the methodology to
12 determine how prescriptions are linked to abuse
13 and how those numbers -- in that methodology,
14 those are in those published studies, and we
15 certainly have a very strong record, I believe,
16 that promotion is -- these drugs are
17 promotionally sensitive.

18 Q. Are all of those studies that you
19 just described cited in your reliance
20 materials?

21 A. Sure. They're not described;
22 they're listed.

23 Q. Is there anything in your report
24 describing the specific -- the methodology

1 specific to Percocet?

2 A. Well, the Percocet section
3 certainly deals with the promotional activities
4 and the promotional goals and I believe their
5 sales numbers. So those things -- that data is
6 in the report.

7 Q. So your methodology as it relates
8 to Percocet is based on the promotional
9 activities described in your report as it
10 relates to Percocet?

11 MR. RAFFERTY: Object to the form.

12 A. So yes. I think we all have to
13 recognize -- and I'm happy if your client
14 can -- it's somewhat limited because of the
15 dates on Percocet. But I have -- with the
16 record that I have in front of me that you've
17 produced on Percocet, yes, that's what I based
18 the decision -- that's what I -- that's what I
19 based the logic on and my conclusions.

■ ■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED] [REDACTED]

1 MR. RAFFERTY: Object to the form.

2 A. That's what it says, yes.

3 MR. RAFFERTY: I'm sorry. I
4 thought you -- okay. I thought you
5 said -- sorry. I thought you misquoted.
6 You didn't. That's my fault.

7 MR. DAVIS: No problem.

8 Q. If Endo spent half that amount to
9 market Percocet, what would the impact have
10 been on reports of abuse?

11 MR. RAFFERTY: Object to the form.

12 A. I have no opinion on that.

13 Q. You can't tell me what the reports
14 of abuse would have looked like had Endo spent
15 half that amount marketing Percocet, correct?

16 A. I've not done that analysis, no.

17 Q. You can't tell me what reports of
18 Percocet would have looked like had Endo spent
19 zero dollars on marketing Percocet from 1999 to
20 2003, correct?

21 MR. RAFFERTY: Object to the form.

22 A. Oh, certainly. I could -- I mean,
23 I could certainly tell you that it would be
24 less. We know these are promotionally

1 sensitive. I've not done the quantitative
2 analysis.

3 Q. You can't tell me how much less?

4 MR. RAFFERTY: Object to the form.

5 A. I've not done the quantitative
6 analysis, no.

7 Q. And the same applies to Opana ER;
8 you've not done any quantitative analysis that
9 links the amount of Endo's marketing budget to
10 specific reports of abuse?

11 A. So there is some data on Opana that
12 we know that -- if I'm correct -- and I have to
13 go back and look on your ROI from your
14 promotional activities.

15 So the areas of the country that
16 you targeted, right, and the program
17 allocations were direct to the areas of
18 greatest ROI, and I don't think I've done -- I
19 do have some of that -- the program allocations
20 for, for example, Ohio. But I have not done
21 that specific quantitative analysis.

22 Q. So had Endo spent half the amount
23 of money it did promoting Opana ER, you can't
24 tell me what the rates of -- how that would

1 MR. RAFFERTY: Object to the form.

2 A. I've not done that analysis the way
3 you've stated.

4 Q. And that analysis is nowhere in
5 your report, correct?

6 A. Well, if I haven't done it, how
7 could it be in my report?

8 Q. Dr. Kessler, you're aware that
9 there was a risk map -- Endo put in place a
10 risk map related to Opana ER, correct?

11 A. The drug would not have been
12 approved without that, correct. It was a
13 requirement of approval.

14 Q. To be clear, at that point in time,
15 FDA did not have statutory authority to require
16 a risk map, correct?

17 A. We could spend a lot of time
18 discussing statutory authority. It may not
19 have been -- there was not -- there were not
20 REMS, I believe, on the 701. FDA had the
21 authority to do risk maps, but again, we leave
22 that to lawyers discussing that.

23 Q. Do you recall a discussion of the
24 ATUs earlier with me, Dr. Kessler?

1 A. You asked me about whether they
2 reflected doctors' perceptions, is what I
3 remember. And I didn't have the actual
4 document in front of me, so I did it from
5 memory.

6 Q. And those reports are referenced on
7 page 132 of your report?

8 THE WITNESS: Gerard, can I just
9 get back --

10 A. What paragraph are we talking
11 about? Let me see if I can find the documents
12 that you're talking about.

13 Q. Specifically paragraph 221.2?

14 A. Do you have the document that's
15 referenced? It would be helpful because I'm
16 not sure my notebook has it.

17 MR. RAFFERTY: 221, Gerard.

18 Q. 221.2.

19 A. I just want to see if I have 437.
20 I don't think I have --

21 THE WITNESS: Parvin, can you just
22 help me see if I can find this document
23 that's referenced -- that Mr. Davis is
24 referring to? I just don't -- if you

1 have it or can pull it up for me.

2 Q. Let's try it this way.

19 question, Dr. Kessler.

20 A. And I respect that, sir. I just
21 want to get my answer -- give me a second to
22 answer your question precisely.

23 So you asked me about materials,
24 correct? Let me just see your question. Your

1 exact question is, you've not seen it in a
2 promotional piece.

3 What I've seen is reports of sales
4 reps -- it says, Many were persuaded to try it
5 because of rep persistence and information they
6 provided and lower abuse potential.

7 But you're correct. I've seen
8 that. I've certainly seen the time X reports
9 in the promotional pieces which talk about
10 time X, which certainly implies lower abuse
11 potential. So I've seen that.

12 Q. Let's try it again.

13 You've not seen any Opana ER
14 promotional piece that contains, quote, low
15 abuse potential, close quote, those words
16 exactly as I've just articulated?

17 A. You're correct. That's not how
18 your company did it.

19 MR. DAVIS: Thank you, Dr. Kessler.

20 THE WITNESS: Thank you, sir, very
21 much.

22 May I ask for a break? Thank you.

23 MS. LEVY: I didn't say we would
24 give it to you; I said you may ask.

1 MR. RAFFERTY: Yes, you can take a
2 break.

3 VIDEO OPERATOR: 10:13, we are off
4 the video record.

5 (Recess from 10:13 a.m. until
6 10:25 a.m.)

7 VIDEO OPERATOR: 10:25, we are on
8 the video record.

9 MR. DAVIS: Dr. Kessler, thanks for
10 your time. I'm done with my questioning
11 for right now.

12 I do want to reserve the right to
13 conduct additional questioning, and
14 object again for the record that the
15 time allotted to defendants, and
16 including Endo specifically, was
17 insufficient, given the scope and
18 content of your report.

19 THE WITNESS: Thank you, Mr. Davis,
20 for your questioning.

21 MR. RAFFERTY: And just for the
22 record, plaintiffs disagree.

23 EXAMINATION

24 BY MS. LAURENDEAU:

1 Q. Dr. Kessler, I'm Amy Laurendeau. I
2 represent Janssen Pharmaceuticals. I'm going
3 to use the time allotted to me to ask you about
4 your numerous opinions regarding Janssen in
5 your report and do the best we can to get
6 through as many as we possibly can in the next
7 few hours.

8 Okay?

9 A. Yes.

10 Q. With respect to Janssen, the
11 opinions you're offering are limited to its
12 three opioid products, Duragesic, Nucynta IR,
13 and Nucynta ER, correct?

14 A. I think that's -- I think that's
15 correct in general with regard to -- I think
16 that's -- with respect to Janssen -- the reason
17 I'm having a little trouble answering that
18 question are some of the facts.

19 Janssen provided, for example, the
20 narcotic for Purdue for OxyContin, and the
21 facts in Janssen's own documents show that it
22 drove the increase in oxycodone. I don't think
23 that's an opinion; I think that's a fact.

24 So I just think that should be

1 on -- that's -- it's clear that, again, from
2 the documents -- the budget documents in Purdue
3 and Janssen's own documents from Noramco --
4 that you developed a super poppy that Purdue
5 bought and, I think it's fair to say, in
6 Janssen's own words, enabled oxycodone to --
7 the extent of oxycodone to be produced.

8 You also affect a significant
9 amount of -- you're the number one narcotic raw
10 material distributor in the world, so there are
11 a lot of -- if we're talking about generic
12 oxycodone and others, I have those sales
13 figures.

14 So again, I think you're relatively
15 right with opinions, but I just want to make
16 sure the record reflects that these
17 relationships among defendants are complex and
18 interconnected, and Oxy would never have --
19 OxyContin would never have flourished the way
20 it did but for Janssen.

21 Q. These aren't issues you intend to
22 testify to at trial, though, are they?

23 A. I'll answer the questions that I'm
24 asked.

1 Q. You haven't said a word about
2 Noramco in your 300-plus page expert report,
3 have you?

4 A. You're right. The documents are on
5 my reliance list.

6 Q. In the 315 pages in which you've
7 listed the facts and opinions to which you
8 testified in this litigation, you haven't said
9 anything about Noramco other than to list it as
10 a defendant, correct?

11 A. I think -- I mean -- I think that's
12 correct on the report. But certainly those
13 documents are on my reliance list and things
14 that I've considered.

15 Q. Are you intending to offer opinions
16 about Noramco and API and Janssen's role with
17 respect to production of API at trial? Yes or
18 no. I need to know today.

19 A. I'm not -- I'm going to answer the
20 questions that I'm asked. Those are facts. I
21 don't think I'm going to -- I'm not going to
22 offer any opinions, necessarily. But those are
23 facts.

24 Q. Well, I'll tell you that Janssen

1 strongly disagrees that those are facts, that
2 everything you say are facts, and so to the
3 extent you intend to testify to those, I need
4 to know.

5 When we allocated time and when we
6 asked for time, there was nothing mentioned
7 about Noramco in the report. I didn't come
8 here prepared to ask you questions about
9 Noramco. Noramco is separately represented in
10 the MDL, and counsel for Noramco isn't even
11 here, since you didn't offer opinions about
12 Noramco.

13 So I need to know what you're
14 intending to say about Noramco at trial, so
15 when I go back to the judge or the special
16 master and ask to either have those opinions
17 stricken or for additional time to depose you,
18 we understand what that testimony and opinions
19 is going to look like from your perspective.

20 MR. RAFFERTY: I'm going to object
21 to the lengthy lecture to the witness,
22 all right. Just ask your questions and
23 he'll answer them.

24 A. So I don't have any specific

1 opinions on Nor -- I mean, on this, but these
2 are facts that I'm certainly happy to address
3 if I'm asked by plaintiffs or defendants, and
4 these facts are well laid out in the reliance
5 materials.

6 MS. FREIWALD: As counsel for
7 Purdue, I just want to join in that
8 objection to the extent what you're
9 saying implicates opinions that are
10 nowhere in your report related to
11 Purdue.

12 THE WITNESS: That's an objection.

13 Q. You're not intending to testify at
14 trial as a fact witness; you're intending to
15 testify as an expert witness, correct?

16 A. That's my intent, right. That's
17 the way I see it. I do recognize, and I leave
18 this to counsel, and I do this somewhat
19 cautiously -- I don't want to get into -- I
20 mean, the fact is that I was at the agency
21 in '93 and '94, for example, and I did take
22 certain actions on one of your products.

23 So I do have firsthand knowledge.
24 I leave it to you and counsel here and the

1 Court.

2 I was retained as an expert
3 witness, and I certainly have been cleared by,
4 as I understand it, by DOJ to testify fully,
5 but I leave it to the Court -- I mean,
6 understand that -- I mean, I leave it to you to
7 characterize me, and I think the best
8 characterization is an expert, but I do want to
9 fully disclose that I am a -- that I do have
10 firsthand knowledge.

11 COUNSEL: Objection.

12 A. I'm sorry, I just want to disclose
13 that I was there. So I just want to make sure
14 that's not in --

15 MR. RAFFERTY: In the interest of
16 time, I'll be happy to discuss with you
17 what our position is on this on the
18 first break.

19 MS. LAURENDEAU: About Noramco?

20 MR. RAFFERTY: Yes.

21 MS. LAURENDEAU: Okay. We'll come
22 back to that, if necessary.

23 Q. You said you've been cleared by DOJ
24 to testify fully. Is that regarding the work

1 that you did on opioids while you were at FDA?

2 A. I have -- I have -- my
3 understanding is that I have no restrictions on
4 me in testifying at trial about opioids on any
5 of the subject matter in this litigation.
6 That's my understanding.

7 Q. Has FDA, to your understanding,
8 waived its privilege with respect to the
9 deliberative process pertaining to opioids in
10 connection with your testimony?

11 A. I would not want to speak for FDA.

12 Q. Has FDA told you that it's waived
13 its privilege with respect to your testimony?

14 A. I do not want to speak for FDA.
15 Those kind of questions -- I've not had any
16 discussions with regard to privilege. I simply
17 asked -- informed HHS, FDA, and DOJ that I was
18 testifying, and I asked in essence whether
19 there was any limitations.

20 Q. And I think you said yesterday,
21 you're not intending to speak or offer opinions
22 on behalf of FDA; to the extent you're
23 testifying or offering opinions here, they're
24 your own personal views and opinions, correct?

1 A. Exactly. Now -- that's exactly
2 correct. If you ask me a question that's
3 factually of what was FDA's view in 1994, you
4 know, I can answer that. I'm speaking for me.
5 I guess I'm speaking for me as former
6 Commissioner. But I may have knowledge of what
7 I said in 1994 as FDA Commissioner.

8 Q. Your report cites and quotes
9 several of Janssen's internal company documents
10 as well, doesn't it?

11 A. Sure.

12 Q. And just as with some of the other
13 defendants you've testified about earlier in
14 your deposition, you're not intending to offer
15 any opinions in talking about those documents,
16 if you're permitted to do so, about Janssen's
17 motivations, correct?

18 A. I -- of course not.

19 Q. You're also not intending to offer
20 any opinions about Janssen's intentions or
21 state of mind to the extent a corporation can
22 have a state of mind, correct?

23 A. Of course not.

24 Q. And that includes any testimony you

1 might give about information expressed in
2 internal e-mails, business plans, or other
3 Janssen company documents, correct?

4 A. Let me just see your question.

5 MR. RAFFERTY: Object to the form.

6 A. Can you restate the question a
7 little?

8 Q. Sure. You're not intending to
9 offer any state of mind or motivation opinions
10 through your testimony about information
11 expressed in Janssen's internal e-mails,
12 business plans, or other company documents,
13 correct?

14 A. Nothing about subjective intent.

15 Q. I'm going to ask you some questions
16 about Duragesic, which I know from your prior
17 testimony you have some familiarity with.

18 Duragesic's indicated for the
19 management of chronic pain, correct?

20 A. Could you -- could we just -- can I
21 trouble you for the label --

22 Q. Sure.

23 A. -- just so I have it so we can --

24 Q. Do you want the initial approval or

1 do you want the current approval?

2 A. Well said. Whichever your question
3 is going to refer to.

4 Q. Okay. Let's show you both then.
5 Because it's -- you're not sure, as you sit
6 here today, without looking at the Duragesic
7 label whether it's indicated for the management
8 of chronic pain?

9 A. Duragesic?

10 Q. Yes.

11 A. That was not what I indicated it
12 for. When I was Commissioner, that certainly
13 was not the indication in 1994.

14 Q. Okay.

15 A. But I just want -- I want to be
16 precise, ma'am. It's not my memory of how --
17 what the intended use was.

18 MR. RAFFERTY: What number is that?

19 MS. LAURENDEAU: This is Exhibit
20 19.

21 (Reporter interruption.)

22 (Exhibit Kessler-19 marked for
23 identification and attached to the
24 transcript.)

1 BY MS. LAURENDEAU:

2 Q. So Dr. Kessler, if you look under
3 the indications and usage for the --

4 MS. LAURENDEAU: Can we turn this
5 on, please.

6 A. Can we just -- can you just help me
7 make sure we agree, this label -- just let me
8 look to the last page, if I can, and see what
9 the date is. Or actually it's sometimes up
10 here.

11 Q. In the bottom right-hand corner it
12 says, Revised September 2018.

13 A. Correct. Thank you.

14 Q. Okay.

15 A. Thank you very much, ma'am.

16 Q. If you look in the indications and
17 usage, it says, Duragesic is indicated for the
18 management of pain in opioid-tolerant patients
19 severe enough to require daily,
20 around-the-clock, long-term opioid treatment
21 and for which alternative treatment options are
22 inadequate.

23 Is that correct?

24 A. That is correct. Not what you

1 asked me prior. That -- your prior question
2 was incorrect. And there lies the rub.

3 Q. Okay. So you wouldn't describe
4 this as being indicated for the management of
5 chronic pain?

6 A. Absolutely not.

7 Q. Okay. Under dosage and
8 administration --

9 A. That's not what that -- that's not
10 what the indication is for.

11 Q. Okay. Under dosage and
12 administration, it states, To be prescribed
13 only by healthcare providers knowledgeable in
14 use of potent opioids for management of chronic
15 pain. Correct?

16 A. That's what dosage and
17 administration says.

18 Q. Okay. Do you have your report in
19 front of you, Dr. Kessler?

20 A. I do, ma'am.

21 Q. Can you look at paragraph 280 of
22 your report, please.

23 A. Paragraph 280?

24 Q. Correct.

1 THE WITNESS: Gerard, can I get --
2 is Gerard there? Can I just get -- if
3 there's a document -- no, there's no
4 documents, so hold it.

5 Q. There's no document; it's just an
6 opinion.

7 A. Yes.

8 Q. You state in paragraph 280 of your
9 report, Spurred by Janssen's marketing, use
10 of Duragesic --

11 A. Just let me get to the actual
12 portion of the paragraph. Spurred by Janssen's
13 marketing -- yes.

14 Q. Use of Duragesic did spread beyond
15 the post-operative period and the healthy
16 cancer patient.

17 A. Yes.

18 Q. That's your opinion?

19 A. Oh, no question about that.

20 Q. Okay. And you believe that
21 expanded use of Duragesic shouldn't have
22 happened, right?

23 A. That expanded use to chronic back
24 pain and osteoarthritis beyond those was

1 off-label unless it -- unless there were no
2 alternative options -- whether alternative
3 options were tried first.

4 The problem is, it expanded to
5 those indications without the requirement that
6 other options be tried first.

7 Q. Okay. So my question was a little
8 bit different. You believe that the expansion
9 of Duragesic beyond the post-operative period
10 and the healthy cancer patient should not have
11 occurred, correct?

12 A. I believe that that's correct, and
13 it shouldn't -- because when you look at what
14 the expansion was, that expansion was not
15 limited to those cases where this -- where the
16 alternative treatments were inadequate. So the
17 expansion into those conditions without that
18 caveat made much of Duragesic's prescribing
19 off-label.

20 Q. And so it's your opinion that some
21 expansion beyond the post-operative period and
22 the healthy cancer patient was okay, but the
23 expansion that occurred was too great. Is that
24 correct?

1 A. I think generally that is -- it's a
2 pretty general statement. I think to be
3 specific, that no one should have been
4 prescribed Duragesic -- if I had any idea that
5 it was being expanded the way it was expanded,
6 I would have -- after I did the label, that was
7 off-label I think is the way I would say it.

8 Q. You believe the expanded use of
9 Duragesic spurred by Janssen's marketing made
10 overdoses and abuse more likely, correct?

11 A. Absolutely. No question in my
12 mind.

13 Q. And the expanded use beyond the
14 post-operative period and the healthy cancer
15 patient made overdose and abuse more likely,
16 correct?

17 A. Sure. The more prescription -- the
18 more promotion, certainly promotion off-label,
19 certainly promotion off-label when other
20 alternatives were not tried, were not required
21 to be tried, that put more drug in interstate
22 commerce, and we know that leads to more abuse.

23 Q. It's within doctors' rights to
24 prescribe any medicines off-label, correct?

1 A. A doctor in his or her judgment may
2 do off-label. I wouldn't want to just say it's
3 in doctors' rights. Certainly under FDA law,
4 that's correct. There are other implications.

5 Doctors are free, subject to other
6 limitations and standards of care, to do things
7 off-label. That's always been the case.

8 Q. FDA certainly doesn't limit doctors
9 from prescribing medicines off-label, correct?

10 A. Generally, that's correct. There's
11 certain restricted distribution drugs, but, you
12 know -- and I think -- but those would be rare,
13 I think.

14 Q. FDA has never restricted doctors
15 from prescribing opioids off-label, has it?

16 A. Oh, I certainly did in Oralet.

17 Q. Okay. Other than Oralet, has FDA
18 ever done anything to restrict doctors from
19 prescribing opioids off-label?

20 A. The Oralet is the one that comes to
21 my mind.

22 Q. And given that you did it in
23 Oralet, that's something that FDA can do if it
24 deems it necessary, correct?

1 A. There's something called restricted
2 distribution when compounds are, in essence,
3 ultra-hazardous.

4 Q. Is that something you as
5 Commissioner of FDA did to restrict the
6 off-label use of Oralet, correct?

7 A. Yes.

8 Q. That's not something, to your
9 knowledge, that FDA has done with respect to
10 any other opioid products, correct?

11 A. I don't, sitting here, recall. I'd
12 have to -- I don't recall, sitting here. I
13 don't know the answer to that question. I'd
14 have to do a little more research.

15 Q. FDA certainly hasn't placed any
16 restrictions on doctors' prescribing of
17 Duragesic off-label, correct?

18 A. I think that -- I think that would
19 be a true statement. I think FDA did,
20 certainly in my statements -- let me just fix
21 my microphone.

22 I wouldn't characterize my
23 statements as restrictions on doctors. There
24 may be a word -- what's a better word than

1 restrictions -- certain caveats to doctors, I
2 think, would be a fair way to characterize what
3 we said back in 1994.

4 Q. You may have given doctors advice
5 or warnings or precautions about prescribing
6 Duragesic, but you never placed any
7 prescriptions -- or any restrictions on
8 doctors' ability to prescribe Duragesic
9 off-label, correct?

10 A. That's correct, ma'am.

11 Q. You also never -- to your
12 knowledge, FDA has never placed any
13 restrictions on doctors' ability to prescribe
14 Nucynta off-label; is that correct?

15 A. That's correct.

16 Q. FDA knew, prior to approval of
17 Duragesic, that it would potentially be
18 prescribed by doctors off-label, correct?

19 MR. RAFFERTY: Object to the form.

20 A. You want to give me the original
21 label so -- I want to make sure -- I wasn't
22 there on the approval of Duragesic, and you're
23 asking me what FDA knew. So I just want to
24 look at the original label if you can give me

1 that.

2 Q. I'll come back to it. That's okay.
3 I have another document I'll show you on that
4 in a bit.

5 Duragesic's approved indication has
6 never been limited to cancer pain, correct?

7 A. The way you phrase it, I think we
8 discussed this yesterday, that's not the
9 phrasing of the indications. The indications
10 are as set out in Exhibit 19. But we certainly
11 were on record with the manufacturer and with
12 the public that we thought that there may be a
13 few instances beyond that.

14 But the understanding -- certainly
15 my understanding was that it was primarily
16 cancer. But I did not want to restrict it, as
17 you said, just to cancer pain. But that was
18 not a wholesale opening.

19 Q. The approved indication was never
20 limited to cancer pain, correct?

21 A. The approved indication is exactly
22 what it says.

23 Q. And the approved indication does
24 not say and has never said that it's limited to

1 cancer pain, correct?

2 A. Correct. But you also have -- you
3 know, you have FDA statements about
4 interpreting where this should be used.

5 Q. I understand that. I'm asking
6 about the approved indication.

7 The Duragesic approved indication
8 has never stated that it's limited to cancer
9 pain, correct?

10 A. I answered that question.

11 Q. I'd like you to answer it again,
12 because I don't think you directly answered the
13 question.

14 A. Yes. I mean, the words of the
15 indication are exactly the words of the
16 indication. And it's not phrased in those
17 terms. The indication is phrased differently.

18 Q. Do you think the words of the
19 indication communicate in different words that
20 the indication is limited to cancer pain?

21 A. I think the words of the
22 indication -- I don't think the indication
23 would preclude all non-cancer pain from any
24 forms of non-cancer pain being used. So no, I

1 think there are some forms of non-cancer pain
2 that the label would allow, but they would have
3 to meet all the requirements of the indication.

4 Q. Is the word "cancer" anywhere -- is
5 it anywhere in the indication for Duragesic, to
6 your knowledge?

7 A. No, it is not.

8 Q. And the FDA could have limited
9 Duragesic's indication to cancer pain, couldn't
10 it have?

11 A. I had -- I made that decision,
12 ma'am, and I made a decision that, as I think I
13 said yesterday, that it was -- it should be
14 used primarily for cancer pain, but we didn't
15 want to restrict it because we saw there may be
16 some other patients that may fit that
17 definition. That's exactly what I said and was
18 communicated publicly.

19 Q. Just to make sure I understand, you
20 specifically made the decision not to limit
21 Duragesic's indication to cancer pain; is that
22 correct?

23 A. Let me get exactly what decision I
24 made so the record is clear.

1 Q. Could you note for the record what
2 you're looking at or reading from?

3 A. I'm reading a 1994 document from my
4 associate, Dennis Strickland.

5 Q. Would you mind if we attach that to
6 the --

7 A. You can put a sticker --

8 Q. -- to the deposition transcript?
9 You can go ahead and read to it, but I'd like
10 to mark it and then take a look at it on a
11 break.

12 (Exhibit Kessler-20 marked for
13 identification and attached to the
14 transcript.)

15 BY MS. LAURENDEAU:

16 Q. You're reading from Exhibit 20 now,
17 Dr. Kessler?

18 A. I am, ma'am. So this talks about
19 the original label, but I mean, I'm reading the
20 fourth paragraph, and halfway down, it says,
21 Consideration was given to limiting the
22 approved indication for the product to the
23 treatment of pain of malignancy, i.e., cancer
24 pain, but it was known that there is a small

1 fraction of chronic pain patients with pain of
2 non-malignant origin who can also potentially
3 benefit from the product.

4 That was a statement that was made
5 after my discussions on the compound.

6 Q. And that was your decision?

7 A. I wouldn't want to say -- I tended
8 not -- I tended to be a pretty
9 consensus-oriented guy at the agency. I think
10 others would probably look at it and say it was
11 my decision.

12 But I can tell you it was -- it was
13 certainly done with the CDER. I would never
14 want to overrule CDER unless I -- there may be
15 rare instances. I think this was a fair read
16 of a consensus of us, but I -- I think I had a
17 little more voting power maybe. But that's
18 what the record shows.

19 Q. You certainly were involved in and
20 agreed with and even had maybe a little more
21 voting power than anyone else with respect to
22 that decision, correct?

23 A. I stand by that decision, yes. I
24 think that -- I still think that is probably in

1 this complex world of, you know, strong
2 opioids, others may differ. I think that
3 that -- I mean, I'm always a little reluctant
4 25 years later, right, I think that's still --
5 those words probably still would be my opinion
6 today.

7 Q. So if I understand your testimony,
8 you do not regret that decision, correct?

9 A. Oh, I certainly regret that
10 decision. I certainly regret that decision.

11 Q. But you stand by it. You think you
12 made the best decision at the time, correct?

13 A. Yeah. If I had any knowledge of
14 your company's several years later marketing
15 for back pain and osteoarthritis, and being in
16 a competitive war with Purdue over this
17 product, I would -- I would certainly have done
18 something differently. I just didn't know
19 that.

20 Q. We talked a bit yesterday about, in
21 2013, the FDA rejected an advisory organization
22 PROP's request to make a distinction between
23 cancer and non-cancer pain in opioid labeling.
24 Do you recall that?

1 A. I remember we discuss PROP. I
2 apologize, I don't remember that specific
3 aspect of discussing it yesterday.

4 Q. Okay. Do you recall that in 2013,
5 the FDA specifically declined -- specifically
6 declined a request to make a distinction
7 between cancer and non-cancer pain in opioid
8 labeling?

9 A. Yeah. I mean --

10 THE WITNESS: Gerard, can you just
11 hand me my general -- sorry, I want to
12 have PROP in front of me, ma'am.

13 Q. I'm just going to move on, because
14 I don't think we have time to get into it.

15 A. Okay. That's fine, but I'm
16 happy -- I just want to pull it up so I can
17 know exactly what the PROP said.

18 Q. Okay.

19 A. But I think that -- I --

20 THE WITNESS: Never mind, Gerard.

21 Q. Duragesic has never been indicated
22 for post-operative pain, has it?

23 A. That's not what the indication
24 says, correct.

1 (Exhibit Kessler-21 marked for
2 identification and attached to the
3 transcript.)

4 BY MS. LAURENDEAU:

5 Q. I'm going to show you the original
6 approval for Duragesic. You just confirmed by
7 looking at Exhibit 19 that Duragesic currently
8 isn't indicated for post-operative pain,
9 correct?

10 A. That's -- I'm sorry. That's not
11 what the indication says, correct, in those
12 terms. It's just the same thing as saying it's
13 indicated for chronic pain.

14 Q. Well, it currently says -- let's
15 take a look at the contraindications in
16 Exhibit 19 for the current Duragesic label. Do
17 you have that in front of you?

18 A. Yes.

19 Q. It currently says --

20 MS. LAURENDEAU: Can we turn this
21 on, please.

22 Q. Under contraindications -- which
23 means Duragesic is not to be used in these
24 circumstances, correct?

1 A. Exactly, ma'am.

2 Q. Acute or intermittent pain,
3 post-operative pain, mild pain. Correct?

4 A. Correct, that's exactly what it
5 says.

6 Q. So it's currently contraindicated
7 in post-operative pain, correct?

8 A. That's exactly what that said. You
9 asked me what the indications were. But you're
10 exactly correct.

11 Q. Okay. And let's look at what I've
12 marked as Exhibit 21.

13 A. Thank you.

14 Q. Which, if you look on the last
15 page, you'll see it's the Duragesic label from
16 August of 1990.

17 A. Thank you very much, ma'am.

18 Q. Under indications and uses, it
19 says, Duragesic --

20 A. I'm sorry, what page are on?

21 Q. We are on --

22 A. These old labels, unfortunately the
23 indications are in the wrong place.

24 Q. It's the actual --

1 A. I don't mean the wrong place, but
2 FDA didn't get it right. Indications -- it's
3 sort of bizarre that they're in the middle of
4 the --

5 Q. It's on the actual third page --

6 A. Thanks --

7 Q. -- not counting the pages on the
8 back.

9 A. Thanks an awful lot, again.

10 Q. Do you see indications and usage
11 now?

12 A. I do, yeah.

13 Q. In the second paragraph,
14 indications and usage, Duragesic is not
15 recommended in the management of post-operative
16 pain, correct?

17 A. Correct.

18 Q. So is it your understanding that
19 Duragesic has never been indicated or approved
20 for post-operative pain?

21 A. Yeah. It's a little more
22 complicated than that.

23 Q. Do you think it was ever indicated
24 or approved for post-operative pain?

1 A. I think that what you read me,
2 again, is, it says, Duragesic is not
3 recommended in the management of post-operative
4 pain. The prior sentence says what it's
5 indicated for.

6 If you changed your question to
7 say, was Duragesic ever recommended for
8 post-operative pain, I would say no.

9 Q. Would it have been -- would it have
10 ever been appropriate, in your opinion, for
11 Janssen to market Duragesic for acute
12 post-operative pain?

13 A. No, because we know that that
14 doesn't meet -- it has to meet the indication
15 statement.

16 Q. Would it have ever been appropriate
17 for Janssen to market Duragesic for use in the
18 post-operative period?

19 A. I want to think about whether
20 there's ever a case for that. I just would
21 want to think about that a little.

22 Q. In January of 1994, I think we
23 talked a bit about the indication in
24 Duragesic's label being updated. Do you recall

1 that?

2 A. Yes.

3 Q. That's the label update that you
4 were personally involved with, correct?

5 A. At that time, yes. I think that's
6 what the record shows and I -- yes.

7 Q. You were -- at the time of the 1994
8 Duragesic label change, you were Commissioner
9 of the FDA, correct?

10 A. Exactly.

11 Q. You were personally involved in the
12 updated label for Duragesic, correct?

13 A. Yes.

14 Q. That was an important issue for
15 you, as Commissioner, to be personally involved
16 with, correct?

17 A. The issue arose out of a tragedy.
18 So that was what was -- so I think the fair
19 answer to your question would be yes.

20 Q. What was the reason for the label
21 change?

22 A. Misuse.

23 Q. What type of misuse?

24 A. Death.

1 Q. Was it -- can you explain any more
2 about the circumstances? Do you recall?

3 A. My recollection -- and again, some
4 of this is refreshed based on the record.
5 My -- my recollection was that someone brought
6 to my attention -- I don't know whether someone
7 in the Commissioner's office brought to my
8 attention or I saw firsthand that there was a
9 young man in Florida who had received Duragesic
10 after dental pain, and there were some issues
11 on -- there were some issues with regard to
12 temperature or a heating pad on Duragesic, and
13 he died.

14 And his mother didn't want that
15 death to, I think, go without -- to be in vain.
16 She wanted other people not to incur that same.

17 So I became aware of that, and
18 obviously, as the record shows -- as Exhibit 20
19 shows, I met on that issue, and that issue led
20 to a broader examination of Duragesic at that
21 time.

22 (Exhibit Kessler-22 marked for
23 identification and attached to the
24 transcript.)

1 BY MS. LAURENDEAU:

2 Q. Okay. I'm going to show you what
3 I've marked as Exhibit 22. Exhibit 22 is an
4 Associated Press article from January 18th,
5 1994 entitled, FDA Says Some Doctors
6 Dangerously Misusing Potent Painkiller.

7 A. Just a second. Show me exactly
8 where you're quoting from.

9 Q. I'm just reading the title of the
10 article.

11 A. Thank you.

12 Right, that's the title.

13 Q. And if you look at the fourth
14 paragraph of the article, you're quoted in this
15 article, correct, or you --

16 A. That's me.

17 Q. An interview you gave is quoted in
18 this article?

19 A. Right.

20 Q. And the quote is, We are seeing an
21 emerging pattern of misuse, FDA Commissioner
22 David Kessler said in an interview.

23 Did I read that correctly?

24 A. You read that exactly correctly.

1 Q. Do you recall believing, as of
2 January 1994, that you were seeing an emerging
3 pattern of misuse with respect to Duragesic?

4 A. My memory is a little fuzzy, but
5 certainly, that is consistent with my memory.
6 I don't -- I mean, I think that -- I mean, I
7 would urge between this letter and the minutes
8 and the letters to Connie Mack. I think they
9 reflect what we knew or saw at the time. I'm
10 not sure I have a lot of memory other than
11 what's in the record.

12 Q. And you certainly don't dispute, as
13 you sit here today, that as of January 1994,
14 FDA was aware of an emerging pattern of misuse
15 with Duragesic, correct?

16 A. No, because obviously, this was
17 used in dental pain, and it was not -- you
18 know, we went through that that was misuse,
19 didn't think it should be used in dental pain.

20 I guess we saw four other deaths,
21 right, one in chronic back pain, one in wisdom
22 teeth, one in sickle cell, and one after a
23 nine-year-old with a tonsillectomy. So that
24 certainly didn't meet the indications as we saw

1 it.

2 Q. These were all situations in which
3 you believed Duragesic was not indicated for
4 use, correct?

5 A. Yeah. I want to be a little
6 careful. I think we found four deaths. I
7 don't have a record exactly on the prescribing
8 history of those or -- for example, on the
9 sickle cell death, for example.

10 I think generally, I would agree
11 with your -- I would say yes to that. But
12 again, the record is a little limited on these
13 cases.

14 Q. Okay. You thought the upgraded
15 warning for Duragesic in 1994 was sufficient to
16 warn doctors of the risks of Duragesic,
17 correct?

18 A. I wouldn't agree with the way you
19 framed your question. I didn't know that it
20 was sufficient -- I mean, I did the best I
21 could, based on what I knew at the time with my
22 colleagues. Clearly, it wasn't sufficient for
23 marketing practices later on.

24 Q. Based on the FDA's information it

1 had, which we know included an emerging pattern
2 of misuse and use in unapproved indications,
3 you did the best you could, and the best --
4 what you thought was appropriate at the time
5 was to upgrade and increase the warnings for
6 Duragesic in 1994, correct?

7 A. I think that's fair.

8 Q. You were Commissioner of FDA for
9 another three years after the Duragesic label
10 change in 1994, correct?

11 A. Approximately.

12 Q. And this remained an important
13 issue for FDA after January of 1994, correct?

14 A. Sure. I mean, every drug and every
15 issue of misuse is important.

16 I will tell you that -- I mean,
17 there are other issues after this that occupied
18 my time. I have no recollection of other
19 interaction on this issue after this.

20 Q. Well, one of the other things
21 you're quoted as saying in this AP article is,
22 quote, This is one of the more striking
23 examples of where we really need to make sure a
24 medicine is being appropriately used.

1 Did I read that correctly?

2 A. That's exactly what I said.

3 Q. Okay. And you believed that to be
4 true as of January 1994, correct?

5 A. Sure. Whenever there's a needless
6 death, I took that very seriously.

7 Q. What steps did you personally take
8 between January of 1994 and February of 1997
9 when you stepped down as Commissioner to ensure
10 that Duragesic was being appropriately used?

11 A. I don't have any recollection,
12 sitting here, of firsthand knowledge. You have
13 to look at the record to answer that question.
14 Obviously, there was the label change. There
15 was the "Dear Doctor." That's what I was
16 involved in. And obviously, the public
17 education. That's what I was involved in.

18 Q. Nothing happened during the
19 remainder of your tenure at FDA that you recall
20 requiring your personal attention on Duragesic;
21 is that correct?

22 A. Correct, ma'am.

23 Q. You certainly expected that the
24 employees working under you at FDA would

1 continue to closely monitor whether Duragesic
2 was being appropriately used, though, correct?

3 A. Sure. But I think the word "we"
4 here -- I think you're overstating it a little.
5 The "we" I think is a collective "we" in that
6 sentence. I would have expected the company; I
7 would have expected doctors. I mean, I was --
8 that "we" is to make sure medicine is being
9 appropriately used, that was as strong a signal
10 as I could give. It's a pretty strong signal.
11 Maybe I could have given a stronger signal to a
12 company and to the world.

13 So I don't think it's just FDA, but
14 I think it's a fair point that those
15 instructions were -- that was an important
16 statement.

17 Q. When you said, We really need to
18 make sure Duragesic is being appropriately
19 used, you meant to include FDA as well as other
20 stakeholders, correct?

21 A. I think everybody would be included
22 in that. I think the pharmaceutical company
23 obviously has primary responsibility to make
24 sure, certainly to the extent -- to the extent

1 that it's controlling its promotion, yes.

2 Q. Okay. I'd like to direct your
3 attention --

4 A. May I give these to the court
5 reporter?

6 Q. Sure, please.

7 A. Thank you very much.

8 MR. RAFFERTY: You need to give
9 yours as well, just the letter.

10 THE WITNESS: I'm going to give
11 this -- I'm giving over my documents.
12 That's fine.

13 Q. If you keep it in the yellow, we'll
14 remember that it's yours and make sure you get
15 a copy back.

16 A. I get it back. Thank you very
17 much, ma'am.

18 Q. I'd like to direct your attention
19 to your report starting on paragraph 273.

20 A. Paragraph 273.

21 Q. Yes. And this is where you're
22 talking about Dr. Curtis Wright's --

23 THE WITNESS: Can I trouble you,
24 Gerard, for that paragraph, please.

1 Q. So this is where you're talking
2 about Dr. Curtis Wright's medical officer
3 review of the NDA for Duragesic, correct?

4 A. Correct.

5 Q. You note that even before reviewing
6 the NDA for Duragesic, Dr. Wright raised
7 concerns with Janssen about diversion of the
8 product, correct?

9 A. That's exactly what I say. But let
10 me just go to the document.

11 Q. I just want to know what you say in
12 your report. I don't need you to confirm with
13 the document right now.

14 A. Okay. Then the report says what it
15 says.

16 Q. Okay. And that's your -- based on
17 your review of the document, that's how you
18 summarized it, correct?

19 A. That's exactly what the report --
20 hold on a second. Let me just -- yes, that's
21 exactly what the report says.

22 Q. And that's your report that you
23 prepared, correct?

24 A. Yes, absolutely.

1 Q. Okay. And so in this medical
2 officer review of the NDA, Dr. Wright --

3 THE WITNESS: Parvin, or somebody,
4 can you just find me this medical officer
5 review, please.

6 A. I'm sorry. I apologize, ma'am.

7 Q. And moving on in that
8 paragraph 273, Dr. Wright, at a pre-approval
9 meeting with Janssen, also asked about the
10 potential for extraction of fentanyl from used
11 or unused system and suggested ways to reduce
12 the abuse potential, including incorporation of
13 naloxone.

14 A. Perfect.

15 Q. So even prior to approval,
16 Dr. Wright at FDA was also talking about abuse
17 potential for Duragesic, correct?

18 A. He was.

19 Q. And in paragraph 275, you note that
20 Dr. Wright noted that once clinicians learned
21 that the system can provide continuous opioid
22 analgesia through the night, the system will be
23 used in a much broader clinical population than
24 intended, correct?

1 A. I'm sorry. I was just looking --
2 I'm there, yes. I'm exactly there.

3 Q. That's what you state in your
4 report, correct?

5 MR. RAFFERTY: I'm going to object
6 to the form. I don't think that was
7 exactly quoted correctly.

8 A. The quote, as I read it, It is the
9 opinion of the reviewer that once the
10 clinicians learn the TTS fentanyl system can
11 provide continuous opioid analgesia through the
12 night, that the system will be used in a
13 broader clinical population than intended.

14 Q. That's something you quote
15 Dr. Wright as noting in his medical officer
16 review, correct?

17 A. I do that.

18 Q. And that indicates that Dr. Wright
19 understood there was a likelihood that
20 Duragesic would be used off-label at some
21 point, correct?

22 A. Oh, no. I mean, again -- there's
23 off-label, and there's off-label, okay.

24 Q. What's the difference between

1 off-label and off-label?

2 A. Oh, there's the off-label that may
3 happen from the anesthesiologist. And Curtis
4 is an ER doc. He's a toxicologist. There's a
5 world of difference between the -- there's a
6 world of difference between the
7 anesthesiologist going in the cabinet and using
8 a product inappropriately, as we know that
9 occupational hazard is, and that's off-label,
10 or a doctor, in his or her judgment, making a
11 decision and promotional campaigns to market it
12 broadly for chronic back pain and
13 osteoarthritis.

14 So there's -- I mean, there's the
15 one-offs off-label, which I -- and then there's
16 the campaigns that are used broadly.

17 So I guess the answer to your
18 question is -- what I meant was the extent.

19 Q. Okay. But Dr. Wright at least knew
20 that there would potentially be some off-label
21 use in what he says a much broader clinical
22 population than intended, correct?

23 A. That's exactly what Curtis said.

24 Q. And Dr. Wright also says, if you

1 look at --

2 A. He put the company on notice, is a
3 fair way to say it.

4 Q. Okay. And he was on notice,
5 correct?

6 A. Sure. I mean, his knowledge put
7 him -- I don't know what that means.

8 Q. Well, he knew it was a potential
9 risk, correct?

10 A. That, I would agree with.

11 Q. FDA was on notice, correct?

12 A. FDA -- Curtis had knowledge, I
13 think is the way to say it best.

14 Q. Curtis worked for FDA, correct?

15 A. Yes.

16 Q. He was the medical officer charged
17 with reviewing the NDA for Duragesic, correct?

18 A. Right.

19 Q. And do you dispute that if Curtis
20 knew something and included it in his medical
21 officer review, that that's something that FDA
22 knew?

23 MR. RAFFERTY: Object to the form.

24 A. I mean, I clearly say Curtis knew

1 this. There's no question, ma'am, that Curtis
2 knew this.

3 Q. And you agree FDA knew it, correct?

4 A. That's a metaphysical question,
5 almost Wittgensteinian in nature. I will
6 certainly -- it's -- for example, just because
7 we're in Washington, when we say the White
8 House knew, who knows what? You've got to be
9 careful on those statements. That's my only
10 issue.

11 I certainly am not taking any issue
12 with the fact that Curtis knew this. In fact,
13 he said to your company he knew this before he
14 even opened the application because he was
15 sensitized to this because he knew the very
16 strong potency of the product.

17 Q. Are you familiar with Janssen's
18 efforts to monitor for abuse, misuse, or
19 diversion of Duragesic?

20 A. I have some familiarity with that.
21 I believe I've seen some documents to that
22 effect.

23 Q. Did you review the deposition
24 testimony of either Gary Vorsanger or Bruce

1 Moskowitz regarding the abuse, misuse or
2 diversion of the efforts to monitor the abuse,
3 misuse or diversion of Duragesic?

4 MR. RAFFERTY: Object to the form.

5 A. I spent more time with Vorsanger, I
6 believe, but I searched both. But Vorsanger I
7 cite in a deposition, and I believe I've spent
8 more time with that, yes.

9 Q. Did you evaluate the risk
10 management plan that was implemented for
11 Duragesic in June 2007 years before the
12 class-wide REMS for extended release opioids
13 went into effect?

14 A. If you can -- can you just give me
15 that risk map so I can just reflect -- refresh
16 my memory on that risk map?

17 Q. I don't have it in front of me.

18 Do you remember if you reviewed it,
19 as you sit here today?

20 A. I'd have to go back and check. I
21 mean, that specific one, I just have to go back
22 and check, ma'am.

23 Q. Are you aware that Janssen had a
24 risk management plan in place for Duragesic

1 years before the class-wide REMS for extended
2 release opioids went into effect?

3 A. That was not uncommon for a number
4 of those compounds.

5 Q. And you knew that Duragesic had a
6 risk management plan implemented years before
7 the class-wide REMS went into effect, correct?

8 A. Yes, I believe that's correct.

9 Q. Did you know, pursuant to the
10 Duragesic risk management plan, that Janssen
11 regularly provided FDA with progress reports?

12 A. That was a part of the risk
13 management -- those are part of the risk
14 management requirements.

15 THE WITNESS: Can I just have
16 the -- pull the risk map if I'm being
17 asked about it.

18 Q. I have very limited time, so I'm
19 just asking what you remember as you sit here
20 today, and you can tell me if you think you
21 need to review it to answer, and that's fine,
22 but I don't have time for you to look at them.

23 A. I just want to be precise exactly.
24 But I am familiar with progress

1 reports, and I have seen progress reports.

2 Q. Okay. Great.

3 And do you recall that the progress
4 reports generally looked for safety signals or
5 new safety signals with respect to misuse,
6 abuse or diversion of Duragesic?

7 A. I think there were sections on
8 that, but I want to review before I give you
9 any opinion on that section of the risk map.

10 Q. In forming your opinions in this
11 case, what, if anything, did you do to measure
12 the rate of abuse, misuse or diversion of
13 Duragesic?

14 A. I don't -- I did not do any
15 specific analysis on that question.

16 Q. Are you relying on any analysis by
17 any of the experts in this litigation?

18 A. I'm not relying on any other
19 experts, but the quantitative aspects of --
20 there are some -- I do have documents that talk
21 about that and the extent of the abuse.

22 I am familiar firsthand with
23 instances of abuse and cases of abuse, but I
24 have not done any specific quantitative

1 analysis of that.

2 And I'm issuing no opinion
3 quantitatively on the specific rate of abuse.

4 Q. Did you review Janssen's cumulative
5 review of iatrogenic addiction associated with
6 the use of the transdermal Duragesic fentanyl
7 patch?

8 A. You'd have to refresh my memory on
9 that document.

10 Q. Okay. I'm going to show it to you.

11 (Exhibit Kessler-23 marked for
12 identification and attached to the
13 transcript.)

14 BY MS. LAURENDEAU:

15 Q. I'll hand you what I've marked as
16 Exhibit 23. Exhibit 23 is a document entitled,
17 Cumulative Review of Iatrogenic Addiction
18 Associated With the Use of Transdermal
19 Duragesic Fentanyl Patch. And it's dated
20 September 8th, 2006.

21 Is this a document you recall
22 reviewing in connection with forming your
23 opinions, Dr. Kessler?

24 A. At the top of my mind, I don't have

1 any -- I'd have to look at the document. I'm
2 drawing a blank on this specific one. I may
3 have. I've got to go take a look. I think
4 it's on -- I'm pretty sure it's on my reliance
5 list, but I'd have to go back and check.

6 Q. Okay. I will represent to you that
7 I did not see it on your reliance list. Would
8 you mind checking on a break and letting me
9 know if you see it or if you think I missed it?

10 A. Yeah. Let me check my -- I have it
11 on my hard drives, and I have much of -- I have
12 much of the submissions to FDA. And the
13 question is, is it in any of those FDA
14 submissions. So I just don't know -- I'd be
15 happy to check and see whether it was part of
16 any of the FDA submissions that are on my
17 reliance list.

18 Q. I'm going to have you look at
19 page 9 very quickly, and show you that page 9
20 evaluated fentanyl patch's exposure from launch
21 to June of 2005.

22 A. I'm sorry. Just show me where
23 you're reading, please.

24 Q. Table 1.

1 A. Table 1.

2 Q. Fentanyl patch's exposure from
3 launch to June of 2005.

4 A. Right.

5 Q. And the total patient days is over
6 1.6 billion, correct?

7 A. That's what that says.

8 Q. And if you look at the results, the
9 results say, the search of sceptor [ph]
10 retrieved a total of 117 cases, with a
11 preferred term of dependence, 14 cases, or drug
12 dependence, 103 cases.

13 Do you see that?

14 A. That's what that says, yes.

15 Q. If the results of this cumulative
16 review of iatrogenic addiction showed a total
17 of 117 cases combined of dependence and drug
18 dependence in more than 1.6 billion patient
19 years, would you agree with me that that's a
20 low rate of dependence?

21 A. Yeah, but --

22 MR. WEINBERGER: Patient days, not
23 patient years.

24 MS. LAURENDEAU: Patient days. Let

1 me restate the question.

2 Q. Would you agree with me that if
3 this report shows a total of 117 cases of
4 dependence in more than 1.6 billion patient
5 days, that that's a low rate of dependence?

6 A. Your question says, if the report.
7 The report says there are 117 cases out of the
8 1.6 billion. And I would agree with you that
9 that would be a low number.

10 But I think everybody would agree
11 that on these reporting systems, these are
12 woefully inadequate and pick up only a
13 fraction, if that, of the total number of
14 cases. They're not that -- these kind of
15 studies are not -- we have this problem with
16 adverse event reporting all the time.

17 So, you know, I would agree with
18 you based on these numbers in this report, as
19 you said, that that would be, you know -- that
20 would come out to the number. But don't hold
21 your breath that the 117 is accurate. I'm
22 sorry.

23 The best way to say it is, the 117
24 is clearly significant underreporting.

1 Q. So even if the actual cases were
2 ten times what was reported, it would still be
3 a low rate of dependence based on the patient
4 days of exposure, correct?

5 A. If that was the number that you
6 hypothesized to use, I would agree with you
7 that that would be low.

8 Q. And you don't know what the actual
9 rate was, but the iatrogenic addiction
10 cumulative review is something that companies
11 and FDA rely on to get a sense of what the
12 actual rate of an adverse event, in this case,
13 dependence, actually is, correct?

14 MR. RAFFERTY: Object to the form.

15 A. No. I think that what you would
16 want to do more accurately is to take a defined
17 cohort of people -- a defined cohort -- and
18 there are studies like this. And you would
19 want to take a cohort that has the number of
20 people who became addicted from prescriptions,
21 and you'd want to be able to understand what
22 they were treated with.

23 So I wouldn't -- this is hypothesis
24 generating, as they say in the trade. This

1 isn't really scientific evidence. There are a
2 whole host of studies that I'm willing to give
3 you on iatrogenic addiction. I mean, again,
4 this is -- I mean, this is what it is.

5 Q. And this is something that FDA
6 actually asked Janssen to do, correct?

7 A. Sure. I mean, this is -- FDA has
8 asked for a whole host of things. This is sort
9 of an epi study. But there are a whole host of
10 studies that are being done that I would say
11 are scientifically -- they'd have a
12 scientific -- they have a more rigorous
13 scientific basis than just simply a signal
14 detection.

15 Q. You said that the actual rate is
16 clearly higher than this. What is the actual
17 rate?

18 A. I don't know. I can tell you
19 that -- I can go through studies about the
20 iatrogenic addiction rate.

21 I think I testified yesterday that
22 if one looked at opioids in general, I was
23 comfortable with about -- you know, from
24 clinical experience, with about 20 percent.

1 But again, I'm happy to go through
2 the literature and show you the range within
3 that literature.

4 MS. LAURENDEAU: Okay. Let's take
5 a quick break.

6 MR. RAFFERTY: Okay.

7 VIDEO OPERATOR: 11:27, we are off
8 the video record.

9 (Recess from 11:27 a.m. until
10 11:43 a.m.)

11 VIDEO OPERATOR: 11:43, we are on
12 the video record.

13 BY MS. LAURENDEAU:

14 Q. Dr. Kessler, can you please turn to
15 paragraph 265 of your report.

16 A. Yes, ma'am.

17 Q. In this opinion, you state that,
18 Janssen contributed to the change in the
19 practice of medicine with regards to pain
20 treatment and the concomitant expansion of both
21 the use and abuse of opioids by misleading
22 promotion and marketing that minimized the
23 risks and overstated the benefits of its opioid
24 drugs.

1 Did I read that correctly?

2 A. You did, ma'am.

3 Q. That's the opinion -- one of the
4 opinions you intend to offer at trial in this
5 case?

6 A. Yes, that would be fair.

7 Q. As I read your report, in this
8 opinion, you're really talking about Duragesic
9 and not Nucynta. Correct?

10 MR. RAFFERTY: Object to the form.

11 A. No.

12 Q. You're talking about both Duragesic
13 and Nucynta?

14 A. I think the majority of the
15 comments, to be fair, relate to Duragesic, but
16 there are certainly issues with regard to
17 Nucynta. But I would agree with you that
18 Duragesic has a significant role in the
19 formulation of that opinion.

20 Q. Is it your opinion that Janssen
21 contributed to the change in the practice of
22 medicine with regards to pain treatment and the
23 concomitant expansion of both the use and abuse
24 of opioids by misleading promotion and

1 marketing of Nucynta that minimized the risks
2 and overstated the benefits of its opioid
3 drugs?

4 A. Yeah, I think that would be fair.

5 Q. Okay. I thought you testified
6 yesterday that the change in the practice of
7 medicine had already occurred at some point in
8 time well before Nucynta was approved.

9 Did I mishear you?

10 MR. RAFFERTY: Object to the form.

11 A. Maybe yes and no. I think what --
12 I think what I said and, hopefully, is
13 reflected in this report -- that activity in
14 the early 2000s, late 1990s set the stage, but
15 I believe that was continued throughout and
16 even after, to the point where --

17 So maybe the question is -- you
18 know, when I use the word "change," maybe I'm
19 not as artful as I should be, but it's the
20 change and that continued change in that
21 perception.

22 So I think that there's an adding
23 on or a perpetuation of that change. Maybe a
24 more artful -- the change and -- perpetuation,

1 not change, may be a more artful way of saying
2 it.

3 Q. So you believe that after
4 Nucynta ER was approved in 2011, the practice
5 of medicine with regards to pain treatment
6 changed as a result of some type of misleading
7 promotion or marketing of Nucynta?

8 MR. RAFFERTY: Object to the form.

9 A. I think it contributed to the
10 overall perception of how opioids was used, and
11 I think that perception was improper.

12 Q. That perception existed well before
13 2007 -- or 2011, correct?

14 MR. RAFFERTY: Object to the form.

15 A. Well, again, I think it's a
16 question of degree, and I mean, it's a question
17 of collectively, over, really, 20 years of
18 that -- that change in perspective from, again,
19 what we knew in 1980.

20 I think -- it's a perpetuation of
21 that change continued, I think is, again, the
22 best way to say it.

23 Q. So you think the practice of
24 medicine with regards to pain treatment would

1 be different than it is today if Nucynta had
2 never been approved and marketed?

3 MR. RAFFERTY: Object to the form.

4 A. I think the -- I think the -- I'm
5 not arguing on its marketing -- I'm sorry. I'm
6 not arguing on its approval --

7 Q. But I'm just saying, assume it was
8 never approved.

9 MR. RAFFERTY: Excuse me. He was
10 answering your question.

11 Go ahead, Doctor.

12 A. I think the -- I think the
13 collective -- I can't quantitate it, but I
14 think the collective perception of opioids as
15 having less abuse potential -- stating, you
16 know, something -- less withdrawal, less GI
17 effects -- I think those things -- and
18 certainly less abuse potential, less
19 withdrawal -- I think those -- that's -- that
20 was a collective -- collectively affected that
21 change in medicine.

22 Q. And you think the practice of
23 medicine today would be different if Nucynta
24 had not been marketed by Janssen in the ways

1 you take issue with?

2 MR. RAFFERTY: Object to the form.

3 Q. That's your opinion?

4 MR. RAFFERTY: Asked and answered.

5 A. I think it was -- I think it was a
6 cumulative thing.

7 Q. And you think the practice of
8 medicine today with regards to pain management
9 would be different if Janssen had not marketed
10 Nucynta in the ways that you take issue with?

11 MR. RAFFERTY: Object to the form.

12 A. I think, again, it contributed to
13 this notion of less abuse potential, less
14 withdrawal for strong opioids. That's what I
15 think.

16 Q. And you think the practice of
17 medicine with regards to pain management would
18 be different today if Janssen had not marketed
19 Nucynta in the ways that you take issue with,
20 correct?

21 MR. RAFFERTY: Object to the form.

22 A. Sure, sure, because people
23 obviously thought they had something, the way
24 your company -- your client, sorry -- marketed

1 this: this had a different withdrawal; this had
2 different tolerability; you could use opioids,
3 but because you have norepinephrine reuptake
4 implications, that you would have opioid
5 sparing.

6 I think that adds to the
7 collective -- the collective way pain was being
8 treated, yes. That marketing -- that marketing
9 has -- marketing by your company had an effect.
10 We know that.

11 Q. I want to focus just on Janssen now
12 and not any of the other manufacturers.

13 How would the practice of medicine
14 be different today if Janssen had not marketed
15 Duragesic and Nucynta in the ways you take
16 issue with?

17 MR. RAFFERTY: Object to the form.

18 A. Oh, I think Janssen -- I think
19 the -- I can show you, just in general.

20 Q. I don't want to know what it did; I
21 want to know how the practice of medicine would
22 be different today.

23 MR. RAFFERTY: Objection. He's
24 answering your question.

1 A. So I think the practice of
2 medicine -- you go back, you know; you look at
3 how opioids were used. Back in 1990s, chronic
4 opioids -- I mean, extended-release opioids
5 were not recommended.

6 1980, that drug of choice book that
7 I showed yesterday, if you look at, for
8 example, this picture, you know, is very
9 different than this picture.

10 And what you see is this sense
11 of -- this perception without data that there
12 would be improved functionality, that this can
13 be used in a broad range of indications such as
14 back pain, in osteoarthritis, I don't think
15 would have ever happened -- I'm sorry -- that
16 would not happen to the extent it would happen
17 but for -- but for marketing.

18 Q. Do you think anything other than
19 manufacturers' misleading promotion and
20 marketing of their opioid products contributed
21 to the increase in opioid prescriptions during
22 the time period you're talking about?

23 MR. RAFFERTY: Object to the form.

24 A. I think that the -- if you're

1 asking me about the increase in prescriptions,
2 I think it was the misleading promotion of
3 manufacturers that contributed to the increase
4 of promotion [sic].

5 Your company specifically had
6 probably the most extensive and most
7 sophisticated system that I've seen on
8 measuring return on investment, measuring
9 return on investment on coupons, on detailing,
10 in Ohio, in Akron, in Cleveland East, in
11 Cleveland West, right.

12 Q. Okay. I --

13 A. So there was no --

14 Q. I understand --

15 MR. RAFFERTY: Hang on. He can
16 finish his question.

17 Q. I have limited time, and you're
18 jumping --

19 A. Sure. I'm sorry. I'm sorry. I
20 apologize.

21 Q. You're going astray.

22 MR. RAFFERTY: You asked --

23 Q. I'm sorry, but you are going
24 astray.

1 MR. RAFFERTY: You know, you did
2 not --

3 A. Go ahead. I'm sorry.

4 MR. RAFFERTY: You asked him a very
5 open-ended question. He can answer.

6 MS. LAURENDEAU: I asked him --

7 MR. RAFFERTY: Otherwise, you can
8 withdraw the question.

9 MS. LAURENDEAU: -- if anything
10 else contributed, and then he started
11 talking about my client's marketing.

12 MR. RAFFERTY: Are you withdrawing
13 the question?

14 MS. LAURENDEAU: No --

15 MR. RAFFERTY: Well, then he's
16 going to finish his question.

17 MS. LAURENDEAU: -- I'm not
18 withdrawing the question.

19 No, he's not.

20 MR. RAFFERTY: Yes, he is.

21 MS. LAURENDEAU: You can object to
22 use of the question later if you want
23 to.

24 MR. RAFFERTY: Move to strike

1 the -- move to strike the question.

2 MS. LAURENDEAU: Okay, great.

3 MR. RAFFERTY: Who was ruling
4 yesterday?

5 BY MS. LAURENDEAU:

6 Q. Did anything other than
7 manufacturers' marketing of their opioid
8 products contribute to the increase in
9 prescriptions, or was that entirely due, in
10 your opinion, to manufacturers' misleading
11 promotion and marketing of their products?

12 MR. RAFFERTY: Object to the form.

13 A. I would never want to state that --
14 I think you used the word "anything." I think
15 there are -- I think that the predominant, the
16 vast, the gravamen, the impetus, the major
17 force, the overwhelming force was the
18 marketing.

19 I mean, I think -- I mean, I do
20 recognize -- and I think I say in this
21 report that I think there were some individual
22 doctors prior to the marketing and promotion
23 that had beliefs that they should be -- they
24 should be used for chronic pain, but I think

1 they were few, they were far between, they did
2 not get traction.

3 You know, would they have -- would
4 those have contributed to an increase? Maybe
5 0.00000001 percent.

6 So when you say "anything," I think
7 there's always things we can talk about, but
8 this was overwhelming. I mean, this is an --

9 Q. You're not --

10 A. This is an epidemic of
11 prescriptions. Again, you asked me what -- if
12 I'm understanding your question -- what
13 resulted in the increase in prescriptions. The
14 prescriptions were promotionally sensitive, and
15 that's what drove these prescriptions.

16 Q. And you think it's the increase in
17 prescriptions that contributed or caused the
18 increased use and abuse of opioids, correct?

19 A. As Dr. Sackler said, the
20 increase -- which I agree, and Curtis Wright
21 has said -- the increased amount of drug in
22 interstate commerce is going to -- put more
23 drug in interstate commerce, you're going to
24 have more abuse.

1 Q. In your opinion, are there any
2 other factors other than the increase in the
3 amount of opioid products in interstate
4 commerce that contributed to the expansion of
5 the use and abuse of opioids?

6 A. Sure.

7 Q. What are those other factors?

8 A. Well, I think we talked about the
9 fact -- I mean, I don't think it's a very big
10 percentage, if you look at the studies, but I
11 think the fact that -- for example, we know
12 that there are bad doctors, there are pill
13 mills, there is -- there are criminals
14 affecting the system.

15 So sure, that's got to have some
16 effect on the abuse other than the increase in
17 the amount of products in interstate commerce
18 that resulted from prescriptions.

19 Q. Have you done any analysis to
20 attempt to determine the percentage
21 responsibility of bad doctors, pill mills, or
22 other bad actors for the increase in the use
23 and abuse of opioids?

24 A. I don't have a specific analysis on

1 that. I do have data -- I mean, you can see
2 it -- and I've looked at specific -- some
3 specific data on how many some -- you know,
4 some of these high-volume docs who get
5 prosecuted, but I have not done any analysis
6 myself of what percentage I can attribute.

7 But my understanding from the data
8 that I've seen, that it's relatively small.

9 Q. You don't intend to offer any
10 opinions at trial on the appropriate allocation
11 of responsibility between manufacturers'
12 purported misleading promotion and marketing of
13 their products versus bad doctors, pill mills,
14 or bad actors for the use and abuse of opioids,
15 correct?

16 MR. RAFFERTY: Object to the form.

17 A. Specific allocations, 22 percent,
18 5 percent, 0.2 percent? No, I would not, not
19 at all.

20 But I think that there should be no
21 mistake that my opinion is that marketing drove
22 this epidemic and the increase of prescription
23 drugs. But I don't have a specific
24 quantitative number for that, no.

1 Q. Your opinion assumes that doctors
2 were actually misled by -- your opinion in
3 paragraph 265 of your report assumes that
4 doctors were actually misled by Janssen's
5 misleading marketing, correct?

6 A. Misled? Sure. I mean, I guess
7 that's probably correct. I'm not sure --
8 doctors follow -- I mean, we know --

9 I just have a little problem with
10 maybe the question "assumes that doctors were
11 actually misled," "actually misled."

12 Q. Well, if they weren't misled by the
13 promotion and marketing that minimized the
14 risks and overstated the benefits of its opioid
15 drugs, then that wouldn't be the cause, as you
16 believe it is, for the expansion of the use and
17 abuse of opioids, correct?

18 A. Yeah, I think that's well said. I
19 would agree that -- if you're defining "misled"
20 like that, I would agree that doctors were
21 misled, because we do know -- and your company
22 has -- knows exactly, in exquisite detail, the
23 return on investment and the promotional
24 sensitivity of virtually all its promotional

1 activities and measured that exquisitely and
2 with, you know, a great deal of sophistication.

3 And we knew those drove
4 prescriptions, and we know those
5 prescriptions -- I mean, a very significant
6 number of those were done, in essence,
7 off-label.

8 So that was -- I mean, because they
9 didn't -- I mean, it could not be that there
10 were no alternatives for this vast number of
11 prescriptions.

12 Q. So your opinion assumes doctors
13 were misled by Janssen's marketing that
14 minimized the risks and overstated the benefits
15 of Duragesic and Nucynta, correct?

16 A. I don't think it assumes anything.
17 I think if you look at the record, if you look
18 at the indication, it is -- the amount of
19 prescribing for chronic back pain and
20 osteoarthritis and the, in fact, back -- the
21 marketing for those clearly shows that that was
22 off-label because it did not have -- that did
23 not include using alternatives showing that
24 alternatives were inadequate.

1 Q. Is it your opinion that every
2 off-label prescription of Duragesic or Nucynta
3 was a result of misleading promotion and
4 marketing by Janssen?

5 A. No. I would never say that all.
6 But just look at your ROI numbers, and you will
7 see the extent and the -- in essence, the real
8 power of your promotional activities for
9 increasing prescribing and, you know -- this
10 was -- I mean, you have a built-in sort of --
11 you want to see the effect of marketing,
12 Duragesic is probably the best example of it.

13 Q. I understand that you've told me
14 that. But I'm really going to ask you to
15 try -- I'm running out of time now, and I
16 haven't asked you about 85 pages of your
17 95 pages of report about Duragesic and Nucynta.
18 So I'll ask you -- we understand your views
19 about this, but I'd ask you to just try to
20 please focus on answering my question.

21 MR. RAFFERTY: Just for the record,
22 he specifically answered your question.
23 He said, no, I would never say that at
24 all.

1 MS. LAURENDEAU: And then he went
2 on and on and on.

3 Q. You would agree that at least some
4 doctors who prescribed Duragesic or Nucynta
5 off-label weren't misled by Janssen's
6 marketing, correct?

7 MR. RAFFERTY: Object to the form.

8 A. I certainly wouldn't want to say
9 that every single doctor. But I think that --
10 there are always exceptions, and there are
11 always individual doctors. But the notion to
12 use this for chronic back pain and
13 osteoarthritis didn't come from any other
14 source other than your marketing.

15 Q. You would agree that some doctors
16 who prescribed Duragesic and Nucynta off-label
17 were well-informed of the risks all along,
18 correct?

19 MR. RAFFERTY: Object to the form.

20 A. Just give me a second to answer
21 that question.

22 Q. What do you need to look at to
23 answer the question, just for the record?

24 A. I just want to see what is -- I

1 want to see something about the label. Hold on
2 a second.

3 Q. I just want to know if you would
4 agree that some doctors were well-informed of
5 the risks of Duragesic and Nucynta all along --

6 MR. RAFFERTY: Object to the form.

7 Q. -- when they prescribed it
8 off-label.

9 A. I think the extent of the -- again,
10 I want it to be precise. I'd want to look at
11 the certain documents.

12 But in the spirit of time, the
13 extent of the addiction from these compounds
14 over the long-term, I don't think the vast
15 majority of doctors -- the exceptionally vast
16 majority of doctors really understood, in light
17 of this change in American medicine that
18 happened.

19 So I don't think the vast majority
20 of doctors were well-informed about the real --
21 I mean, after these -- I mean, these campaigns
22 that minimized collectively the abuse of these
23 products. So, I mean, I think -- I'm not
24 saying there's no one who's well-informed, but

1 I think it was very small.

2 Q. You would agree that at least some
3 doctors were well-informed of the risks all
4 along, correct?

5 A. I am sure that there are a couple
6 who resisted this notion that you could use
7 these drugs safely in these conditions.

8 Q. You think there are only a couple
9 doctors who were well-informed of the risks of
10 Duragesic and Nucynta but prescribed those
11 products occasionally off-label for certain
12 patients?

13 MR. RAFFERTY: Object to the form.

14 A. I do need to find -- so I can be
15 precise.

16 Q. I'm just going to move on.
17 Withdraw the question.

18 THE WITNESS: Go off the record for
19 a second.

20 MR. RAFFERTY: She's moved on,
21 Doctor.

22 THE WITNESS: Thanks.

23 A. I just want to be able to answer
24 your question precisely.

1 Q. Do you have an opinion, as you sit
2 here today, of how many doctors who prescribed
3 Duragesic and Nucynta -- what percentage who
4 prescribed Duragesic or Nucynta off-label were
5 misled by Janssen's misleading promotion or
6 marketing?

7 MR. RAFFERTY: Object to the form,
8 asked and answered.

9 THE WITNESS: Why don't we go off
10 the record. I just need to find one
11 document, and I don't want to take your
12 time.

13 MS. LAURENDEAU: Okay. We'll go
14 off the record.

15 VIDEO OPERATOR: 12:06, we are off
16 the video record.

17 (Recess from 12:06 p.m. until
18 12:11 p.m.)

19 VIDEO OPERATOR: 12:11, we are on
20 the video record.

21 BY MS. LAURENDEAU:

22 Q. Dr. Kessler, do you have an answer
23 to the pending question?

24 A. Yes. I don't have a -- I have no

1 opinion on a precise percentage of doctors who
2 prescribed Nucynta were misled. But I think it
3 was a very significant number who were affected
4 by the minimization of the risk of abuse. I
5 think that change in medicine had a major
6 impact on the profession.

7 Q. Can you name anyone, as you sit
8 here today, who prescribed Duragesic or Nucynta
9 who was misled by Janssen's promotion and
10 marketing and otherwise would not have
11 prescribed the medicine?

12 MR. RAFFERTY: Object to the form.

13 A. Yeah, I'm -- I did not conduct, nor
14 would I think it would be appropriate to do, an
15 anecdotal interview. That's not -- I mean, I'm
16 basing it on the data that I have seen.

17 Q. You haven't spoken with anyone,
18 whether in an anecdotal interview, in the
19 course of your professional career, or through
20 any formal survey or otherwise, who indicated
21 to you that he or she prescribed Duragesic or
22 Nucynta as a result of being misled by
23 Janssen's marketing or promotion, correct?

24 MR. RAFFERTY: Object to the form.

1 A. I wouldn't rely on the anecdotal
2 kind of comments that are just made to me. I
3 think that would be inappropriate.

4 Q. And you're not aware of anyone who
5 fits that description, as you sit here today,
6 are you?

7 MR. RAFFERTY: Object to the form.

8 THE WITNESS: Gerard, can I just
9 see General 1, please.

10 MS. LAURENDEAU: What's General 1?

11 THE WITNESS: Just my notes,
12 please. Just the packet of notes.

13 MR. RAFFERTY: Can I ask a
14 question?

15 MS. LAURENDEAU: Sure.

16 MR. RAFFERTY: When you say, you're
17 not aware of anyone, you mean by name?

18 MS. LAURENDEAU: Any. Any specific
19 person. I know he holds the opinion
20 that that's generally true. I want to
21 know if he has any specific person he
22 knows of who falls into that category.

23 A. So let me give you a call note that
24 provides evidence in Cuyahoga. And it ends in

1 just 4, and everything prior is Janssen, Ohio
2 ending in 4.

3 Quote, Duragesic for chronic back
4 pain and DJD, degenerative joint disease,
5 believed was only used for cancer patient.
6 Discussed patients on Percs and Vics and how to
7 convert, gave core message of our Duragesic,
8 disc. MS, Oxy. Said he would choose Duragesic
9 over them.

10 So that's obviously a change. I
11 can give you the doctor's name here, but I
12 don't think that would be fair.

13 Q. Was that a doctor in Cuyahoga
14 County, you said?

15 A. In Cuyahoga County. I'm just
16 reading from call notes.

17 Q. What was the date of the call note?

18 A. 4-14-1999.

19 (Reporter interruption.)

20 Q. And that was a discussion about
21 chronic back pain and DJD, correct?

22 A. Correct.

23 Q. That was within the approved
24 indication for Duragesic at that time, correct?

1 A. Yeah.

2 Q. No.

3 A. No.

4 Q. You think it was only approved for
5 cancer pain?

6 A. No.

7 Q. What was it approved for at the
8 date?

9 A. You could use it in chronic back
10 pain, but you can only use it in chronic back
11 pain when there was no other alternative. That
12 was the indication. Continuous, around the
13 clock. That's the rub, ma'am.

14 Q. How do you know that patient didn't
15 require continuous, around the clock and hadn't
16 had other medications fail?

17 A. That's certainly -- you can -- we
18 only know what we see here. Obviously, this
19 call note says this doctor changed; that
20 Duragesic was for chronic back pain and DJD.

21 You're right in terms of, if this
22 said Duragesic for chronic back pain when no
23 other alternatives and continuous and around
24 the clock. But if -- you know, if that was the

1 indication that it was being promoted for, it
2 would have said that.

3 Q. Well, and you don't know what the
4 doctor actually did in response to this
5 information provided by the sales rep, do you?

6 A. I'm limited to the fact that he
7 says he would choose Duragesic, thought -- over
8 Oxy, as the last sentence. So I know what he's
9 saying. He's saying now he will choose that.

10 I do not know, you're correct, what
11 scripts this individual -- but I could run --
12 I'm sure I have that in the IMS if you want to
13 take a look.

14 Q. You haven't spoken to that doctor,
15 correct?

16 A. I think that would be
17 inappropriate. So obviously, I'm relying on
18 the record, correct.

19 Q. Okay. And other than this example
20 from call notes, are you aware of any doctors
21 who you believe -- you've given me one
22 example -- prescribed Duragesic or Nucynta and
23 wouldn't otherwise have prescribed it as a
24 result of Janssen's misleading promotion and

1 marketing?

2 A. Well --

3 MR. RAFFERTY: Object to the form.

4 A. You certainly have documents -- I'm
5 happy to give you all of them and cite them --
6 that the driving the functionality story versus
7 Oxy, that message --

8 Q. Rather than --

9 MR. RAFFERTY: Objection.

10 Q. Rather than general messages or
11 general activities, I'm focused on specific
12 doctors right now.

13 Other than the one example you've
14 given me from call notes, are you aware of any
15 instances of any doctors who prescribed
16 Duragesic and Nucynta and otherwise would not
17 have were it not for Janssen's misleading
18 promotion of the products?

19 MR. RAFFERTY: Objection. I think
20 it's vague, and that's the problem.

21 It's -- you're saying "instances."

22 A. I mean, I can tell you -- I can
23 give you -- and the way that your client did
24 this was in the aggregate so that there was --

1 Q. What are you looking at, for the
2 record, please?

3 A. So I can give you a number of
4 documents. You want to put those on the --

5 Q. I just want you to identify what
6 you're looking at, and then I'll decide if
7 we're going to talk about it or not.

8 A. Okay. One is called Duragesic
9 E-Detailing Pilot Program. One is Key Tactics
10 Review. One is Duragesic -- Duragesic Coupon
11 ROI Analysis NRx and Coupon Data Through 2001.
12 And the Ohio Regional Business Plan 2009.

13 Q. These are documents that you're
14 relying on for your opinion that Janssen's
15 misleading promotion and marketing of Duragesic
16 or Nucynta caused doctors to prescribe opioids
17 and they otherwise would not have, correct?

18 MR. RAFFERTY: Object to the form.

19 A. I'm relying on -- that opinion that
20 you just stated, I'm relying on all the
21 documents that I cite in the report, not just
22 these, just so you understand.

23 Q. But these documents don't provide
24 any examples of specific doctors who have been

1 misled by Janssen's promotion or marketing of
2 Duragesic or Nucynta, correct?

3 A. I think these doctors provide
4 better evidence than an individual doctor
5 because that's --

6 Q. That's fine.

7 A. Let me finish my statement.

8 Q. We can quibble about that, but --

9 A. They do. Because they give you
10 exactly the return on investment from
11 promotion -- various promotional activities.
12 And we know what those promotional
13 activities -- what they were for and how they
14 were misleading.

15 So you have the numbers in
16 aggregate, what the effect is of your
17 promotion, and even in Cuyahoga County and in
18 Summit -- in cities in Cuyahoga and Summit.

19 Q. But without talking to an
20 individual doctor, you can't testify that any
21 particular doctor was or wasn't misled, can
22 you?

23 MR. RAFFERTY: Object to the form.

24 Q. You have to assume that they were?

1 A. No, I'm not assuming anything.
2 What I'm relying on is your company's analysis
3 of how doctors changed their prescribing
4 practices based on the promotional materials
5 that were given and the promotional sales
6 pitches that were given that focused on
7 functionality, et cetera, that we've discussed.

8 Q. And it's your opinion that those
9 doctors who prescribed Duragesic and Nucynta
10 were misled, correct?

11 A. Certainly, the campaigns that
12 focused on functionality, on lower abuse that
13 are identified in the report, those campaigns
14 led to the misleading of doctors.

15 Q. And in order for a doctor to be
16 misled, they had to give more weight to
17 Janssen's marketing than to the product
18 labeling, correct?

19 MR. RAFFERTY: Object to the form.

20 A. Janssen's -- Janssen's marketing
21 was so extensive and so sophisticated that it
22 wasn't just, quote, marketing. So it's not a
23 question of --

24 Q. Can you answer my question. Either

1 you agree with me or you disagree with me.

2 A. I will.

3 Janssen's -- it's not a question of
4 Janssen's just, quote, marketing. Janssen got
5 doctors and studied extensively which doctors
6 influenced other doctors.

7 So it wasn't a question of
8 whether -- you know, some sense of Janssen
9 marketing, but in sort of -- between KOLs and
10 KOL mapping was just exquisitely sensitive.
11 The range from regional advisory boards to the
12 speakers' bureaus, to the E-marketing to
13 doctors, to the alternative channels, to the
14 advocacy groups, to the unbranded publication
15 plans, you knew exactly which KOLs would
16 influence which doctors to prescribe, and your
17 client utilized those KOLs to influence.

18 So it's -- the sophistication of
19 what influenced doctors versus the label, the
20 label had no chance compared to the
21 sophistication that your company utilized to
22 market because you got other doctors in KOLs to
23 talk to those doctors and changed American
24 medicine.

1 Q. Is it your opinion that these
2 activities you've just described made it
3 impossible for doctors to be aware of the risks
4 of opioid medicines and particularly Duragesic
5 and Nucynta in deciding whether to prescribe
6 them?

7 A. You infiltrated the medical
8 profession in such a way that it was very hard.
9 You got other doctors to talk -- the most
10 influential, the ones that you said would score
11 five or six on your KOL mappings. The most
12 influential doctors you got to talk to other
13 doctors to talk about things that changed,
14 again, the practice in regard to opioids. So
15 it became -- it was overwhelming in nature and
16 highly sophisticated.

17 Q. Did these activities make it
18 impossible for well-informed doctors to
19 understand the benefits and risks and make
20 appropriate prescribing decisions regarding
21 Duragesic and Nucynta for their patients?

22 A. Made it impossible. I would never
23 say anything made it impossible. That would
24 be -- but do not -- do not underestimate the

1 extent to which you infiltrated American
2 medical practice.

3 Q. Okay. In terms of -- you have some
4 opinions in your report about potential
5 direct-to-consumer advertising for Duragesic,
6 starting at paragraph 286.

7 Do you recall that?

8 A. I do.

9 Q. Okay. Did Janssen ever undertake a
10 direct-to-consumer marketing campaign for
11 Duragesic?

12 A. It decided not to, after it --
13 well, it decided not to do DTC broadcasts.
14 Let's put it that way.

15 Q. And it's true that after several
16 meetings with FDA, Janssen listened to FDA's
17 concerns and did not undertake a
18 direct-to-consumer advertising campaign for
19 Duragesic, even though FDA didn't prohibit it
20 from doing so, correct?

21 A. Well, FDA was bound by the First
22 Amendment. So, you know, that's -- make no
23 mistake that that's what the issue is here.
24 Just so we understand, that's DTC broadcasts.

1 There certainly --

2 Hold on one second. Let me just
3 check one --

4 Q. It's okay. I'll move on. I
5 understand your question. You're looking for
6 something to potentially clarify.

7 In the context of discussions with
8 FDA, Janssen informed -- if you look at
9 paragraph 287 of your report, Janssen informed
10 FDA that it was looking to market Duragesic
11 to back pain and arthritis sufferers, correct?

12 A. I apologize. I just have to get my
13 report. Just give me a second.

14 Q. In the context of --

15 A. What paragraph, please?

16 MR. RAFFERTY: 287.

17 Q. Paragraph 287.

18 A. Thank you very much. I'm sorry.

19 Q. In the context of discussions with
20 FDA about potential direct-to-consumer
21 advertising of Duragesic, Janssen informed the
22 FDA it was looking to market Duragesic to back
23 pain and arthritis sufferers, correct?

24 A. I'm sorry. Market Duragesic to

1 back pain and arthritis sufferers as
2 undertreated. Is that what you're reading
3 there?

4 Q. I'm not reading it; I'm summarizing
5 it.

6 A. Let me just read it, then.

7 Q. Did you answer --

8 A. I'm just not done. I apologize.
9 I'm a slow reader. I apologize.

10 THE WITNESS: Can I get the actual
11 document on 287, Gerard, please.

12 Q. Let me just talk about what you've
13 written about it here.

14 A. Sure.

15 Q. So you reviewed the document, and
16 you wrote a summary paragraph in your report,
17 correct?

18 A. Correct.

19 Q. And you've described it as saying,
20 Janssen's representative clarified that
21 Janssen's, quote, market research had
22 identified back pain and arthritis sufferers as
23 undertreated and potentially appropriate
24 candidates for Duragesic, correct?

1 A. That's exactly what the document
2 says.

3 Q. And DDMAC's representative
4 responded to Janssen and said, quote, this was
5 fine, but the message needs to be clearer that
6 the drug is for severe pain, not your everyday
7 back pain, correct?

8 A. That's exactly what that says.

9 Q. And so Janssen informed FDA it was
10 looking to market Duragesic to back pain and
11 arthritis sufferers, correct?

12 MR. RAFFERTY: Object to the form.

13 A. At what point in time are you
14 talking about?

15 Q. I'm talking about in connection
16 with this -- discussions in May of 2000 about
17 Janssen's direct-to-consumer advertising plan
18 for Duragesic.

19 A. Right. So again, this is in
20 context to DTC, but obviously, what you
21 intended as part of your -- your NDA. This is
22 just one conversation that is going on in the
23 context of broadcast.

24 Q. Right. And so in the discussions

1 pertaining to DTC, Janssen informed FDA one of
2 the things it wanted to advertise to consumers
3 was pertaining to use of Duragesic for
4 arthritis pain and back pain, correct?

5 A. Correct.

6 Q. And FDA didn't say, no, you can't
7 do that, did it? FDA said, this is fine, but
8 the message needs to be clear that the drug is
9 for severe pain, not, quote, your everyday back
10 pain. That's what FDA said, right?

11 A. That's what's said in this memo.
12 What FDA -- obviously, what Nancy Ostrove is
13 bound by the label, so you can't take this
14 as --

15 Q. I'm just talking about what FDA
16 said.

17 A. We can certainly say in the context
18 of discussing whether you should do DTC, Nancy
19 Ostrove was -- her recollection was that you
20 would target cancer pain, right?

21 It's interesting because that was
22 exactly my recollection at the agency, and that
23 was my sense of what Duragesic was for, that
24 there may be some patients, but they would be

1 few. And this again, this is the rub.

2 You wanted to market for chronic
3 back pain and arthritis.

4 And FDA -- I said it, and Nancy
5 Ostrove is saying, be careful here. This is
6 not -- this has to meet those indications in
7 essence on the label, and she's using shorthand
8 and saying, you know, this is not your everyday
9 back pain. This better be continuous. This
10 better be continuous; this better be when -- in
11 essence, when there's no other alternatives.

12 Q. Did the FDA ever send Janssen a
13 warning letter or untitled letter for marketing
14 Duragesic for non-cancer pain?

15 A. It sent other letters. I don't
16 believe -- again, the answer is no, because
17 that's not what the label says. That's not
18 what the indication -- it couldn't send a
19 label [sic].

20 Q. Right. So FDA wouldn't send an
21 untitled letter, a warning letter, or take
22 enforcement action against Janssen for
23 marketing Duragesic for non-cancer pain because
24 the label permitted it to do so, right?

1 A. No. I mean, it would have sent a
2 warning letter, right, if it knew that you were
3 prescribing this -- if you were marketing this
4 for non-continuous, non-around-the-clock,
5 non-cases where other alternatives were not
6 tried first. I mean, unless that is prominent
7 in your promotion, there should have been a
8 warning letter. That's what it was indicated.

9 That was the line that I tried to
10 walk. I tried to give room outside of cancer,
11 right. But it had to be where there were -- no
12 other alternatives would work.

13 Q. You knew even when you were
14 Commissioner this was a potential issue,
15 correct, and a fine line to walk?

16 A. I had no idea you would get into a
17 competitive war with Purdue and open this up to
18 chronic back pain and arthritis and not the
19 most severe, limited cases.

20 Q. Okay. I'm going to -- I have
21 limited time left, so I'm going to ask you a
22 few questions about Nucynta.

23 A. Let me just get some of this out in
24 front of me. Just give me one second.

1 Q. FDA was aware, even before Nucynta
2 was approved, about the growing abuse crisis,
3 correct?

4 A. I'm sorry, are you saying FDA?

5 Q. Yes.

6 A. I think that's fair, of course.

7 Q. And FDA was concerned about
8 potential for abuse with Nucynta before it was
9 approved, correct?

10 A. Absolutely.

11 Q. Are you aware that Janssen
12 submitted all of its promotional materials for
13 Nucynta to DDMAC or OPDP?

14 A. I'm not going to take issue with
15 it. The only thing I would say that I -- the
16 record doesn't reflect that that's -- it
17 doesn't mean that FDA reviewed it.

18 Q. Okay. Is it your opinion that
19 Janssen -- or that FDA may not have reviewed
20 all of Janssen's promotional materials for
21 Nucynta, even though Janssen provided them?

22 A. That's usually the practice. And
23 in the vast majority of promotional materials
24 that get submitted, certainly after launch,

1 would not get reviewed.

2 FDA, in certain periods of time,
3 certainly, you know, had a handful of people,
4 maybe four or five, I think the GAO report
5 cited. It would be impossible for FDA to
6 review everything that was -- FDA could not --
7 I mean, there was a very small fraction that
8 FDA would review of submitted materials. That
9 differs a little on launch.

10 Q. Do you know -- you don't know, as
11 you sit here today, whether FDA actually
12 reviewed Janssen's promotional materials for
13 Nucynta, correct?

14 A. I can see what's in -- in the -- in
15 the record. I -- top of mind, I don't recall
16 at this moment.

17 Q. And FDA's never expressed concern
18 with Janssen's marketing materials for Nucynta,
19 has it?

20 A. So there's a 2011 letter, I
21 believe, if my memory serves me right, that I
22 would need to get in front of me.

23 Q. That letter pertains to statements
24 made by -- at a conference by one sales rep,

1 correct?

2 A. You need to show me the letter, but
3 I will take your stipulation, in the spirit of
4 time. The letter says what the letter says.

5 Q. FDA never issued a warning letter
6 related to Nucynta marketing materials, did it?

7 A. It was only that one letter, ma'am.

8 Q. And that was an untitled letter,
9 correct?

10 A. Again, I don't have it, but I think
11 you're right.

12 Q. Okay. I'm going to ask you -- I
13 guess I'm going to jump back to a few of the
14 letters you talk about from FDA to Janssen
15 regarding Duragesic.

16 THE WITNESS: Gerard, can I get my
17 notebook that's called DDMAC Janssen,
18 please.

19 Q. So starting at -- I believe it's
20 paragraph 301 of your report, you talk about
21 warning letters that the FDA issued to Janssen
22 regarding Duragesic.

23 A. Hold on one second, please.
24 Paragraph 301.

1 Q. 301 talks about a September 2004
2 warning letter to Janssen regarding a file
3 card, correct?

4 A. Yes.

5 Q. And paragraph 304 talks about a
6 March 5th, 1998 DDMAC warning letter to Janssen
7 regarding promotional posters for Duragesic,
8 correct?

9 A. Yes, ma'am.

10 Q. That letter was actually an
11 untitled letter, wasn't it?

12 A. Did I make a mistake on the March
13 5th letter, are you saying?

14 Q. I believe you did.

15 A. Okay. Then I'll take your
16 correction on that 19 -- the letter says what
17 it is. I take -- I'll take notice on it.

18 Q. And in paragraph 305, you reference
19 a March 30th, 2000- --

20 A. Let me just put a footnote. 19 --
21 yeah, let me clarify the answer to that
22 question. As I said earlier, the issue back at
23 that time, and I have to refresh my memory,
24 don't take the title of the letter as -- at

1 different points in FDA's history, we titled
2 these things -- I certainly titled this
3 differently.

4 If you go to the last page on page
5 3 of this 1998 letter, it says, Janssen should
6 immediately suspend all promotional activities,
7 and Janssen should submit a written response on
8 or before March 20th.

9 The general rule in compliance and
10 the general rule in the industry, when you are
11 being -- you should -- and gives you a date to
12 do this, that -- I'm not sure FDA in 1998 made
13 a distinction, but I think it's fair to call
14 this in -- I use a little W in paragraph 304,
15 and I would stand by that, by the nature of
16 this letter and the way it's written.

17 We just went back and forth,
18 although we had warning letters, we had
19 different title letters and different points in
20 time had different policies.

21 Q. Okay.

22 A. Clearly it was a warning letter, a
23 little W, warning letter.

24 Q. Okay. The -- I'm going to ask you

1 some questions about the 2004 warning letter.

2 I guess before I do that, can you
3 look at paragraph 306 where you're offering
4 some opinions about call notes of Janssen sales
5 reps?

6 A. What are we on, 304?

7 Q. 306.

8 A. 306. Thanks, ma'am.

9 THE WITNESS: Can I get my book on
10 306, please.

11 Q. So in paragraph 306, you state that
12 the call notes of Janssen's sales
13 representatives show that into 2004, they were
14 frequently promoting Duragesic to prescribers
15 for lower back pain and arthritis, correct?

16 A. Yes.

17 Q. And for that, footnote 625, you
18 cite 11 calls in 1998, four calls in 1999, one
19 call in 2003, and 11 calls in 2004, correct?

20 A. That's exactly what I say. And I
21 also say, see also schedule 11.

22 Q. And so you cite specifically to 27
23 calls, correct?

24 A. I had to add them up. I've got to

1 look how many are in the schedule. I have
2 not -- I mean, I can do that now, but I don't
3 want to take the time.

4 Q. And these examples are where you
5 say, Frequently promoting Duragesic to
6 prescribers for lower back pain and arthritis,
7 these examples you cite are out of how many
8 calls did Janssen sales reps make to potential
9 Duragesic prescribers during this at least
10 six-year period that's encompassed by your
11 review?

12 MR. RAFFERTY: Object to the form.

13 A. I'd have to go check that. I can
14 go back and check the number of call notes that
15 I had access to.

16 Q. And you note that some of these
17 calls indicate that sales representatives were
18 also citing to the Milligan and Simpson studies
19 referenced in the sales bulletins noted above
20 in promoting Duragesic for lower back pain,
21 correct?

22 A. Correct.

23 Q. And for that you cite one example,
24 correct?

1 MR. RAFFERTY: Object to form.

2 A. That's what the report states.

3 Q. Okay. Are you aware --

4 A. I don't think there's any question,
5 right. I think you look at the totality of
6 evidence here, your client was certainly
7 promoting this for chronic back pain. I mean,
8 the ads themselves show that.

9 Q. And that was consistent with the
10 indication, correct?

11 A. No, of course not.

12 Q. Okay.

13 A. Chronic back pain, either take
14 Nancy Ostrove or take my -- when there's no
15 other alternative therapy, when it's severe and
16 around the clock, the whole thing was not to do
17 this -- I mean, not to open the door. That was
18 the change.

19 Q. Okay.

20 (Exhibit Kessler-24 marked for
21 identification and attached to the
22 transcript.)

23 BY MS. LAURENDEAU:

24 Q. I'm going to hand you what I'm

1 marking as Exhibit 24.

2 A. Thanks.

3 MR. RAFFERTY: What number is this?

4 MS. LAURENDEAU: 24.

5 MR. RAFFERTY: Thank you.

6 A. This is the -- this is not the
7 200- -- I'm sorry, I have 1998 here; is that
8 correct?

9 Q. I gave you the wrong one then,
10 sorry.

11 A. I'm sorry if I -- I have 200- --

12 Q. No, I gave you the wrong one. Let
13 me switch that.

14 A. Okay, thanks.

15 Q. Sorry about that. Here's 2004,
16 Dr. Kessler.

17 A. Thank you so much, ma'am.

18 Q. Okay. So this letter on page 3 is
19 talking about a file card, and it's --

20 A. Do you want me to just --

21 THE WITNESS: Parvin, can you just
22 pull up the file card out of here -- or
23 somebody just pull up the -- Lesi -- I'm
24 sorry, I apologize -- just pull up the

1 file card so I have that at the same
2 time.

3 MR. RAFFERTY: What page are you
4 on?

5 MS. LAURENDEAU: Page 3.

6 Q. Under Conclusions and requested
7 actions, the letter states, The file card makes
8 false or misleading safety claims or
9 unsubstantiated effectiveness claims for
10 Duragesic, correct?

11 A. I just want to -- yes, that's what
12 it says.

13 Q. Okay. And isn't it true that false
14 and misleading is used by the FDA to mean
15 there's no substantial evidence or substantial
16 clinical experience to support the claim?

17 A. False or misleading can mean a
18 number of things.

19 Q. And FDA uses false or misleading to
20 mean there's no substantial evidence or
21 substantial clinical experience to support the
22 claim, correct?

23 A. No. It's more complicated than
24 that. False or misleading could be the

1 admission of certain facts. It was the net
2 impression we talked a little about yesterday.
3 So it's more -- substantial evidence is
4 certainly a part, but I wouldn't want to say
5 that false and misleading equals substantial
6 evidence when it's used.

7 I mean, if you don't give a fair
8 balance, for example, that could be -- there
9 are whole things that go into what's misleading
10 and omissions, and it's defined in the regs.

11 Q. Okay. As it relates to the safety
12 claims made in the file card, FDA isn't saying
13 here that Janssen provided no evidence to
14 support the safety claims in the file card.
15 It's saying that it shouldn't have relied on
16 the DAWN data to support the claims, correct?

17 MR. RAFFERTY: Object to the form.

18 A. Hold on one second. Just let me
19 see. You're reading that in the -- hold on one
20 second.

21 Q. I'm not reading from the document;
22 I'm summarizing the issue. If you don't
23 remember, that's fine.

24 A. No, no, no, I remember this. I

1 just don't remember every single sentence.

2 Just give me one second.

3 This is not just about DAWN data.

4 This is also about claims about functionality,
5 and your company was fully aware that it did
6 not have appropriate data and evidence with
7 regard to functionality. I think that's also
8 in this letter.

9 Q. Okay. If you go through the
10 letter, each of the claims that FDA takes issue
11 with, it says, we're not aware of substantial
12 evidence or substantial clinical experience to
13 support this claim.

14 A. Certainly that's -- with regard to
15 functionality, your company didn't have that
16 evidence. That's correct.

17 Q. Okay. As it relates to the safety
18 claims, Janssen relied on DAWN data, correct?

19 A. Well, I -- sometimes these
20 effectiveness claims are safety claims. But
21 depending on what -- how you're characterizing
22 it, it certainly dealt with DAWN data and the
23 issue of lower reported rates of abuse. That's
24 what it's relying on for that section.

1 Q. Well, FDA broke down this warning
2 letter into false or misleading safety claims
3 and unsubstantiated effectiveness claims,
4 correct?

5 A. But it did not break that down in
6 the conclusions and requested actions that you
7 read me. It's using false -- it says, False or
8 misleading safety claims and unsubstantiated
9 effectiveness claims. So again, depending on
10 where you think that false or misleading
11 modifies, it could be both.

12 Q. Have you reviewed Janssen's
13 response to the 2004 warning letter regarding
14 Duragesic?

15 A. I may have seen it. I tend to try
16 to do that. But I don't have it -- I don't
17 recall, sitting here.

18 Q. Do you recall that Janssen agreed
19 to remove the file card from its circulation?

20 A. I believe that's correct.

21 Q. And Janssen agreed to issue a
22 correction letter?

23 A. I'm fully aware of that.

24 Q. Okay. And FDA didn't take any

1 further action with respect to the claims in
2 the 2004 warning letter, did it?

3 A. I believe that's correct, after the
4 corrective action was taken.

5 Q. FDA didn't bring any type of
6 enforcement action against Janssen, did it?

7 A. It did not.

8 MS. LAURENDEAU: Okay. I am
9 unfortunately out of time, so out of
10 respect to my co-defendants and to give
11 them time with you, I obviously, like
12 those who came before me and those who
13 will come after me, would just like to
14 note that I have much, much more that I
15 would like to do with you, and
16 particularly given my conversation with
17 Mr. Rafferty on one of the breaks about
18 testimony you may give regarding
19 Noramco, which essentially he just said
20 you're going to testify to what -- or
21 potentially testify to what you told me,
22 which I understand you view as facts, we
23 view as opinions, and we view as facts
24 and opinions or alleged facts and

1 opinions that were not in your report
2 and we weren't on fair notice that you
3 were intending to testify as to those
4 subjects.

5 So we reserve all rights, including
6 the right to ask for the opportunity to
7 continue with the fun and depose you
8 again on another date prior to trial.

9 THE WITNESS: Let me say
10 something --

11 MR. RAFFERTY: And to just --

12 THE WITNESS: Thank you, Counselor.
13 I'm sorry.

14 MS. LAURENDEAU: Thank you.

15 MR. RAFFERTY: Yeah. And just for
16 the record, obviously, we disagree with
17 the assessment in terms of the time and,
18 in terms of the assessment, in terms of
19 the issue regarding the super poppy.

20 I think -- it was disclosed, we
21 believe it's facts, and we'll deal with
22 it later, I guess.

23 MS. LAURENDEAU: Thank you,
24 Dr. Kessler.

1 THE WITNESS: Thank you, Counselor.

2 May I take a break? Actually, we
3 may take a bigger break, right?

4 VIDEO OPERATOR: 12:49, we're off
5 the video record.

6 (Recess from 12:49 p.m. until
7 1:41 p.m.)

8 VIDEO OPERATOR: 1:41, we are on
9 the video record.

10 EXAMINATION

11 BY MR. GALLAGHER:

12 Q. Dr. Kessler, good afternoon. My
13 name is Richard Gallagher, from Ropes & Gray,
14 counsel for Mallinckrodt.

15 A. Good afternoon, Mr. Gallagher.

16 Q. Are there any opinions relating to
17 Mallinckrodt that are not set forth in your
18 report about which you intend to testify at
19 trial?

20 A. No, I don't think so. I think all
21 my opinions are -- well, either in my report
22 or -- if we stop -- if you want to stop now, I
23 would say the answer is, my report.

24 If you ask me questions, I may have

1 opinions, obviously, to your questions that you
2 ask. So -- but we can discuss those.

3 But again, it's anything that I --
4 in my report or to which I testify with you
5 this afternoon, sir.

6 Q. Okay. So sitting here right now, I
7 can be confident that what you've written in
8 your report captures what you intend to testify
9 about at trial with regard to Mallinckrodt; is
10 that correct?

11 A. Yeah. I mean, I think the report
12 aims to do the four corners, but there's a lot
13 of material that we may end up talking about.
14 I think there is -- again, I think there is --
15 it doesn't change my opinions.

16 I mean, there's one point that I
17 think is a little factual, but it depends
18 whether you ask me, and I'll be happy to tell
19 you about it. Your call. But it's not -- I'm
20 not going to give a different opinion.

21 But documents say certain things,
22 and they're on -- they're on my reliance list,
23 to the extent to which you want me to point
24 them out. They may not be fully stated in the

1 report.

2 Q. Do you recall the two branded
3 products from Mallinckrodt that are the subject
4 of your report?

5 A. Exalgo and Xartemis? I mean, I've
6 never pronounced it correctly. I apologize.

7 Q. I may not have either.

8 A. Yeah. So we're both -- we're both
9 in the same boat.

10 Q. Sitting here right now, do you
11 intend to render opinions at trial on brands
12 other than those two from Mallinckrodt?

13 A. No. Well, see, you use the word
14 "brands." I think that there is the issue of
15 generic oxycodone that I do think is referenced
16 within the scope of my report. I think, just
17 to -- that's certainly not in the sections on
18 Exalgo and Xartemis --

19 How are we going to refer to it?

20 Q. Xartemis?

21 A. Yeah, that's fine. Thanks.

22 So they're not Exalgo and Xartemis,
23 but there is a section of the report -- to the
24 extent the collective defendants engaged in

1 class-wide opioid promotion, sort of unbranded
2 promotion, that had an effect not only on the
3 brands that we -- Exalgo and Xartemis, but also
4 had an effect on generic oxycodone.

5 So to the extent that in sales,
6 that affected generic oxycodone, that's in the
7 report.

8 Q. Is there a section of your report
9 that describes this phenomenon?

10 A. Yes, there is. It's discussed
11 pretty extensively in the report that much of
12 the unbranded advertise -- sorry -- the
13 unbranded promotion that took place was about
14 opioids, less abuse, pseudoaddiction. Much of
15 that -- that sort of rose the water level, if
16 you would, for the whole class.

17 So that rising the water level
18 affected not only the name brands but obviously
19 the generics, and your client was a very
20 significant generic manufacturer.

21 Q. Why don't we go to page 20 of your
22 report.

23 A. Yes, sir.

24 Q. Do you see where there's a heading

1 that says, Promotional information needs to be
2 evaluated by the totality of the impression it
3 creates?

4 A. Exactly.

5 Q. And you see there's a citation to
6 the FDA's industry guidance?

7 A. Correct.

8 Q. Is that the standard you applied to
9 come to a conclusion as to whether promotional
10 materials were misleading or not?

11 A. That's one of the factors that is
12 used in the evaluation. This is how you
13 evaluate risk communication specifically in
14 promotional materials.

15 But there are other aspects, such
16 as overstatement of efficacy, understatement --
17 so there are other -- there are other aspects
18 and standards that are also set out in this
19 section that --

20 But when it comes to risk
21 communication, I think that would be fair.

22 Q. Would it be risk communication to
23 doctors?

24 A. Depends what the promotion is aimed

1 at, I think would be a fairer statement, sir.

2 Q. Before the break, you talked about
3 the collective impression of doctors and gave
4 testimony about that. Do you recall?

5 A. Yes.

6 Q. You've given a lot of testimony
7 about, in your opinion, promotional activities
8 that you believe were misleading.

9 Who do you believe that those
10 activities or statements misled? Is it
11 primarily the doctor community?

12 A. That's a good question. Let me
13 think for a second, if I may.

14 As it relates to prescribing
15 behavior and that change in prescribing
16 behavior, I think it is -- it's doctors, it
17 would be nurse practitioners, it would be those
18 who had prescribing, you know, responsibility.

19 But I think it changes. I think
20 it's a little broader. I think it would be
21 health professionals, I mean, who were -- who
22 receive promotional messages. So it would be
23 the target audiences of those promotional
24 messages.

1 Q. So when you talked about collective
2 impression that was made by promotional
3 activities, you were talking about a category
4 broader than doctors; is that fair?

5 A. Well, they certainly -- yes. I
6 think it's fair to say the promotional messages
7 you see in the campaigns affected pharmacists,
8 nurse practitioners, managed -- you know, a
9 whole range of individuals who are health --
10 who touch the health care system. I think you
11 see various campaigns directed against
12 different professionals.

13 Q. Are the professionals that matter
14 in terms of prescriptions the professionals
15 that write prescriptions?

16 MR. RAFFERTY: Object to the form.

17 A. Primarily, yes. As I said
18 yesterday, I'm not getting into -- I'm not
19 going to testify about pharmacists, but you
20 certainly --

21 You know, just answering your
22 question fully, the pharmacists certainly
23 matter when it's -- when we're talking in terms
24 of prescriptions, because they're the ones

1 that -- they're professionals who fill those
2 prescriptions. So they matter, sir.

3 Q. The heading says that, Promotional
4 information needs to be evaluated by the
5 totality of the impression it creates.

6 Do you see that?

7 A. Yes.

8 Q. What does that mean, "the totality
9 of the impression"?

10 A. So what FDA -- the old DDMAC, you
11 know, the regulations and -- is that you
12 can't -- if you have a number of different
13 components of information, for example, on a
14 sheet, you have to look at the graphics, you
15 would have to look at the audio, you would have
16 to look at the words.

17 If I say, you know, This drug, you
18 know, causes leukemia, and somebody's walking
19 on the beach and the ad -- and the sound is the
20 music and everything, you just have to look at
21 all those -- you should look at all those
22 factors that are absorbed by the -- you know,
23 the person to whom that promotion is aimed at.

24 Q. Would you also consider the label

1 or materials outside of the promotion being
2 examined?

3 A. Say that again. I'm sorry.

4 Q. Would you also -- in doing this
5 assessment of the totality of the impression,
6 would you look at the label and consider the
7 information conveyed by that?

8 A. Generally, in DDMAC, you know, you
9 would do this by the -- I mean, I think you
10 would probably consider it, but obviously, a
11 6-point font on the last page is not going to
12 be considered in the impression that the first
13 six pages of a sales aid in 40-point font and
14 color would have.

15 You know, so generally, when one is
16 talking about the material, it's per -- it's
17 per -- what's the best way -- it's per -- per
18 impression, right.

19 So it's the impression of the piece
20 that conveys, and it's usually the aid itself,
21 but I wouldn't want to exclude the label, if
22 it's attached.

23 Q. You said before the break that you
24 don't believe that the vast majority of doctors

1 were well-informed of the risks in addition to
2 the benefits.

3 Do you remember that testimony?

4 A. I remember something generally.

5 MR. RAFFERTY: Object to the form.

6 A. I don't remember the exact
7 testimony.

8 Q. You testified, I'll represent to
9 you, that you don't believe that the vast
10 majority of doctors were well informed of the
11 risk in relation to the benefits of certain of
12 certain products.

13 Do you believe that was the case
14 for the two Mallinckrodt products that you've
15 given opinions about?

16 A. So we can take them separately. I
17 think there were misleading characteristics
18 of -- that I point out and that were, you know,
19 again, part of this, you know, less peaks,
20 smoother, less -- and what that conveyed with
21 regard to lower abuse potential.

22 So were they really informed of the
23 risk? So that would diminish their information
24 of the risks.

1 Q. When you say "they," who are you
2 talking about?

3 A. No, you had -- the question was,
4 that I'm reading, do you believe that the vast
5 majority of doctors are really informed of the
6 risk of the product really informed of the risk
7 of the product?

8 Q. So when you --

9 A. So I'm talking about -- I'm
10 sorry -- about doctors, sir. So it would be
11 who would be --

12 For example -- I mean, in the
13 paragraphs, I point out that certain graphs
14 give an impression about peaks and troughs, and
15 that sort of implies that it's safer, and that
16 means that you're not fully informed.

17 Q. So you personally believe that
18 doctors weren't well-informed of the risks from
19 the Mallinckrodt products?

20 A. I think that the standard -- no,
21 the way I would say it is, there are certain
22 requirements that the information needs not --
23 it's important it not convey misleading
24 information because we know that --

1 The reason we have that sort of
2 requirement is because that -- I mean, it's
3 sort of given that if you're misleading in the
4 ads, doctors are not well-informed.

5 I don't have a survey on
6 particularly -- on each point, but I can tell
7 you that's the reason why the standard is what
8 the standard is.

9 Q. Why don't you have a survey on each
10 point?

11 A. Well, because I'm sort of limited
12 to the record.

13 And there are surveys, and in
14 certain manufacturers, I can tell you exactly
15 doctors' perceptions, I can tell you what the
16 return on investment, I can tell you what the
17 effect of this promotional campaign or this
18 promotional element is on the number of
19 prescriptions. I can even do that to a certain
20 city.

21 But it depends on what the record
22 has, sir.

23 Q. What surveys have you undertaken
24 with regard to doctors' impressions of

1 Mallinckrodt products?

2 A. I restricted this report to the
3 record. I've not gone outside of the record.
4 I was not asked to do that, and I've not done
5 that.

6 Q. Do you have any objective evidence
7 of what doctors believed about Mallinckrodt's
8 products?

9 A. Sir, let me just -- let me just
10 refresh. So there are -- for example, you
11 have --

12 With regard to Mallinckrodt and
13 Exalgo specifically, I can tell you what the
14 message recall was at a certain -- at certain
15 points in times based on, you know, certain
16 data.

17 So there are those -- you know, the
18 unaided message recall, whether there was a
19 recall that there was less abuse, misuse,
20 overdose potential.

21 There is some information about
22 what the doctors' recall was after -- sorry --
23 after promotion.

24 Q. So that's the evidence that you

1 have about the collective impression of doctors
2 about Mallinckrodt products?

3 MR. RAFFERTY: Object to the form.

4 A. I mean, that is what you have, both
5 the strategy documents and what the message
6 development is and what the recall is. I mean,
7 that's among what I have.

8 But if you want to measure it, you
9 would measure it by recall, and that's what I
10 have, and I'm limited to what the company has.

11 Q. Do you have any objective
12 information about doctors' collective
13 impressions of the risks that would arise for
14 Mallinckrodt's products?

15 A. Only to the extent that in those
16 recall documents, those message recall
17 documents -- minimal, less abuse -- a certain
18 percentage had that impression -- that recall.

19 What was the main message of the --
20 and, again, I'm going to apologize -- is it
21 Covidian [ph] or Covidan [ph] -- of that sales
22 representative conveyed about Exalgo.

23 So we know what their impression
24 was from those message recalls.

1 Q. And those collective recalls are
2 all you have on that point; is that correct?

3 MR. RAFFERTY: Object to the form.

4 A. I'd want to go back to review my
5 report. I mean, any information I have is in
6 either my report or in the reliance list.

7 Q. Did you become aware of a survey of
8 Ohio physicians on opioid prescribing behaviors
9 in connection with your work on this matter?

10 A. I've become -- I'm not sure. Top
11 of my head, I just don't have a memory right
12 now. I've seen certain documents, but I'm not
13 sure I've seen what you're referring to.

14 Q. When you began work on this matter,
15 did you ask to receive all information which
16 would provide information about how doctors
17 perceived risks from Mallinckrodt's products?

18 MR. RAFFERTY: Object to the form.

19 A. No, I didn't ask specifically that.
20 I didn't want to be fed information. I
21 insisted that the entire database be given to
22 me so -- unencumbered. I may at certain times
23 have asked for certain things, but I searched
24 the database.

1 Q. Did you search the database for
2 survey information about doctors' mental
3 impressions?

4 A. I'm not sure I put those mental
5 impressions in. I may have used recall
6 messages, other things. Those kinds of surveys
7 I may have either asked for, but I didn't
8 use -- I don't believe I would have used the
9 word "mental impression." It's not something
10 that -- it was not the lingo of the recall
11 surveys that I'm used to seeing in the
12 industry.

13 Q. Do you have any expertise in
14 analyzing how consumers will assess and
15 interpret information that's disclosed to them?

16 MR. RAFFERTY: Object to the form.

17 A. Yes. I mean, I have been -- you
18 know, I had to make the hard call sometimes,
19 and not the only one, but does FDA bring an
20 enforcement action whether something is false
21 or misleading, and, you know, what the evidence
22 one needs if one is going to do a misbranding
23 action.

24 I was the guy who seized orange

1 juice because it was fresh, right. So I mean,
2 I had to understand exactly that question of
3 how it was perceived.

4 So I mean, I've both taken a
5 marketing course, you know, in business school
6 as well as had to do it on the job.

7 Q. So you made enforcement decisions
8 at FDA relating to where you had to make
9 judgments about perception of consumers in the
10 market. Is that fair to say?

11 A. I think -- I mean, I don't want to
12 say that I did this alone. I certainly did it
13 with my colleagues at the agency. But at the
14 end of the day, they go, Kessler, what are you
15 going to do here? In a number of instances,
16 what do you want me to do? And I would make
17 the decision. But that would be rare.

18 I don't want you to think that
19 that's the run-of-the-mill kind of
20 decision-making the agency where the
21 Commissioner is making decisions, but I
22 certainly have made those decisions.

23 Q. So do you believe that at the FDA,
24 where employees make enforcement decisions,

1 that makes them experts on consumer
2 understanding of information?

3 A. Well, you know you're going to be
4 the named defendant in court, you better be an
5 expert, because if I'm going to take an
6 enforcement action, my name is going to be as
7 the defendant, I mean, or my boss' name is
8 going to be -- the Secretary is going to be
9 named as defendant. So you learn pretty
10 quickly and pretty thoroughly when you're on
11 the line here.

12 And again, I had some training on
13 marketing. I've also -- there was a lot of --
14 all of DDMAC really is the question of what's
15 false or misleading, you know.

16 I tried hard to do it the best I
17 could. I think I learned a lot. I certainly
18 think I understand it in the context of FDA
19 regulation. I may not know it in terms of the
20 jolly green giant, right, and -- but I think in
21 terms of FDA-regulated products, I probably
22 understand false or misleading with the best of
23 them.

24 Q. So you believe your understanding

1 of whether or not doctors receive false and
2 misleading information about Mallinckrodt's
3 products is just as good as if you had
4 undertaken an objective survey to answer that
5 question?

6 A. No. It's different information. I
7 mean, it's different information. I have the
8 information. I have -- I can look at a piece
9 and say, it looks false or misleading. It
10 conveys certain impressions. Especially when
11 that piece is in context.

12 In this case in Exalgo, when you're
13 talking about peaks and troughs, we know that
14 that -- that those promotional messages ended
15 certain people up, you know, in criminal
16 violation.

17 This was out of a -- I don't know
18 what the right word is -- out of a -- I want to
19 be careful here. I mean, these messages -- I
20 don't want to say script, I don't want to say
21 playbook -- these messages sort of -- did we
22 that we see early on about lower abuse
23 potential, less peaks, less troughs, that
24 impression, that was a theme, I think, through

1 these opioid products, and so it's in the
2 context of that. This is not just a one-off.

3 I think if I saw your -- saw
4 something just one slide alone, it's one thing.
5 But one slide in the context of these themes
6 where these themes are adjudicated in essence
7 even criminally as misleading, even with their
8 unique aspects, I mean, it's that totality of
9 that evaluation.

10 Q. What FDA enforcement -- what
11 enforcement -- FDA enforcement actions are you
12 aware of involving Mallinckrodt's two branded
13 products that you opine on?

14 MS. FREIWALD: Object and move to
15 strike the part of the answer that
16 misrepresents the record.

17 A. I'm not sure I opine -- everything
18 that I'm opining on with regard to -- is in the
19 report, and I don't believe there is any
20 enforcement action. I don't have a memory of
21 any enforcement action.

22 Q. So if the FDA decided not to pursue
23 enforcement action against Mallinckrodt for
24 these two branded products, by your standards,

1 should we conclude that there was no
2 misrepresentation in the promotion?

3 A. Of course not.

4 Q. How is that consistent with what
5 you told me earlier?

6 A. Well, first of all, FDA doesn't
7 catch everything. Limited resources. I mean,
8 you know, not everybody gets caught for
9 speeding, right. Just because you don't get
10 cited doesn't mean you're home free and you're
11 not false or misleading.

12 Q. What have you done to test the
13 FDA's resources and its impact on the ability
14 to bring enforcement actions against
15 Mallinckrodt?

16 A. I can't tell you anything specific
17 with regard to Mallinckrodt. I can tell you
18 that the record is full of documents that shows
19 FDA's resources specifically in the DDMAC area.
20 Both the General Accounting Office as well as
21 the Institute of Medicine has studied this
22 extensively with regard to the industry as a
23 whole, and the FDA's resource -- I mean, those
24 reports deal with the totality of resources FDA

1 has to deal with Mallinckrodt and everyone.

2 Q. When you were doing your work in
3 relation to your opinions on Mallinckrodt, did
4 you ask to see all marketing and promotional
5 materials that Mallinckrodt had made available?

6 MR. RAFFERTY: Objection, that's
7 work product. Communications between
8 the expert and the attorney are clearly
9 out of bounds.

10 Q. Did you?

11 MR. RAFFERTY: No, do not answer
12 that question.

13 MR. GALLAGHER: Are you taking the
14 position that there is a work product
15 privilege between counsel and this
16 expert?

17 MR. RAFFERTY: Yes.

18 MR. GALLAGHER: And you're
19 instructing him not to answer the
20 question?

21 MR. RAFFERTY: I am.

22 Q. Did you think it was important in
23 doing your work to review all promotional
24 materials in the production about Mallinckrodt?

1 A. I thought it was important to have
2 the full database available to me. I tried to
3 review as many documents as I could, as it was
4 humanly possible within, you know, reasonable
5 time constraints of life.

6 So I did ask for the entire
7 database, but there are millions and millions
8 and millions of pages, that it was just beyond
9 my capability.

10 So I did search. It was important
11 for me to see the strategies as well as those
12 promotional materials that were -- that was
13 important. So I tried. But there's a limit to
14 what I -- I don't -- you can't see every
15 promotional piece.

16 Q. So it's fair to say that you did
17 not review all of the Mallinckrodt promotional
18 materials, correct?

19 MR. RAFFERTY: Object to the form.

20 A. I had access to that. I wouldn't
21 want to sit here today -- I don't have a
22 recollection of exactly -- I mean, I've looked
23 at thousands and thousands and thousands of
24 documents, including numerous Mallinckrodt

1 documents, and many were promotional materials,
2 but I can't tell you what percentage I looked
3 at or all or -- and I just -- I don't have that
4 memory.

5 Q. So you don't know?

6 A. Exactly, sir.

7 Q. Did you come across Mallinckrodt
8 promotional materials that accurately disclosed
9 the relevant risk relating to the two products
10 about which you opine?

11 A. I think there are aspects of --
12 there's aspects of the promotional materials
13 that I don't have any objection to. I think my
14 report points out the ones that I do. I don't
15 want to say that they're all -- all those
16 statements are misleading, no. I point out the
17 ones that are misleading.

18 Q. Why did you not include in your
19 report disclosures that accurately described
20 risks?

21 A. Well, I can't -- the reports are
22 350 pages. I tried my best to include as much
23 as I could. But I can't -- you can't describe
24 everything, Counselor. I mean, I just --

1 The issue here -- the central issue
2 to me that I focused on were issues of
3 especially abuse liability, this change in
4 medical practice, how we became -- the medical
5 profession ended up prescribing these more
6 loosely and overcoming -- what had to be done
7 to overcome that fear of addiction. So that's
8 what my report in significant part focuses on.

9 And I think with regard to
10 Mallinckrodt, I talk -- the issues that I deal
11 with are, you know, focus on certainly I think
12 less abuse liability.

13 MR. GALLAGHER: I have no further
14 questions, Dr. Kessler.

15 For the record, I'm ceding the
16 balance of my time; for the reasons that
17 the parties have discussed throughout
18 this deposition, the manner of the
19 questioning, compressing the time
20 available for all the defendants, so I
21 join and Mallinckrodt joins in the
22 objection relating to them.

23 MR. RAFFERTY: Plaintiffs take the
24 same position. No, no, let me rephrase

1 that. That might not read right.

2 Plaintiffs disagree.

3 MS. LEVY: And for the record, on
4 behalf of the other defendants who have
5 not yet gone, we dispute the
6 characterization of ceding time. I
7 think you mean you're passing the
8 witness. But as we would dispute the
9 division of time, I think that you might
10 have cut into our time, not ceded us
11 extra time. But we can discuss that.

12 MR. GALLAGHER: I don't mean to
13 imply that we are having our time stolen
14 away from us, but that the circumstances
15 are requiring us to share time.

16 MS. LEVY: Thank you for
17 clarifying.

18 MR. GALLAGHER: Dr. Kessler, thank
19 you.

20 THE WITNESS: Thank you, Counselor.
21 Can I ask who's going next.

22 MR. GALLAGHER: Off the record.

23 VIDEO OPERATOR: 2:13, we are off
24 the video record.

1 (Recess from 2:13 p.m. until
2 2:23 p.m.)

3 VIDEO OPERATOR: 2:23, we are on
4 the video record.

5 MS. FEINSTEIN: Thank you.

6 EXAMINATION

7 BY MS. FEINSTEIN:

8 Q. Good afternoon, Doctor. We met
9 briefly before the deposition. I'll
10 reintroduce myself for the record. My name is
11 Wendy West Feinstein. I represent the Teva
12 defendants in this litigation.

13 I'll be asking you some questions,
14 and as we've all noted, we have limited time,
15 so I'd request that you do your best to listen
16 to my questions and answer as concisely as you
17 can, okay?

18 A. Thank you, ma'am.

19 Q. Thank you.

20 So before we get started on the
21 substance, I want to understand the scope of
22 your report with respect to my client regarding
23 not only the scope of the products that you're
24 covering, but also the time scope.

1 So as I look at your report, I see
2 two products that you reference, Actiq and
3 Fentora; is that right?

4 A. Yes.

5 Q. And you render opinions with
6 respect to Actiq and Fentora, but no other Teva
7 or Cephalon products, right?

8 A. Correct.

9 Q. Earlier today you mentioned that
10 there are a lot of company changes with many of
11 these organizations, and so you focus more on
12 products than company names; is that right?

13 A. Well said.

14 Q. Just to clarify for the record,
15 some of the documents that you reviewed have
16 the Cephalon name on them, right?

17 A. Correct.

18 Q. And those relate to Actiq and
19 possibly Fentora; is that right?

20 A. Yes.

21 Q. When today, if I use the phrase
22 "Teva," can we understand that to include
23 Cephalon?

24 A. Thank you.

1 Q. And you will agree with me that
2 that --

3 A. Yes.

4 Q. -- phrase will cover both?

5 A. Yes.

6 Q. Do you also render any opinions
7 with respect to any of the companies that Teva
8 acquired that manufacture generic opioids that
9 are also defendants in this litigation?

10 A. The only generic oxycodone that I
11 think is in the scope has to do with
12 Mallinckrodt. There is obviously the issue of
13 generics from Actavis and others, but -- so the
14 answer that I gave to your prior colleague I
15 think would hold across the board here. And I
16 can just restate it so it's clear.

17 To the extent the opioid
18 manufacturers contributed to a change in the
19 prescribing of opioid -- the class of opioids,
20 that would refer to affect both branded --
21 especially unbranded promotion is going to
22 raise the prescription level of both branded
23 and generics.

24 But that -- that's the -- that's

1 sort of where I -- where I enter an opinion on,
2 that when you do unbranded promotion for a
3 class, and that class is opioids as opposed
4 to -- I'm going to apologize, I'm going to
5 probably use the word "Actiq."

6 Q. That's fine.

7 A. But Actiq or Fentora, then it
8 affects all, including the generics, and that
9 is covered in the report.

10 Q. So just to make sure that I
11 understand your opinion and so that we have it
12 clear on the record, any opinion that you
13 render related to generic opioids would also
14 apply to any branded opioids that are not
15 involved in this litigation but that benefitted
16 from what you have opined is improper unbranded
17 marketing by the defendants in this litigation?

18 A. I have to admit --

19 MR. RAFFERTY: Object to the form.

20 A. -- ma'am, you've just stumped me.
21 My head is spinning. I apologize. I just --
22 maybe it's the hour. I don't know if we're at
23 hour 12 or so, not consecutively, but I just
24 didn't follow. There are too many unbrandeds

1 and brandeds in there.

2 Q. So you have no separate opinion
3 with respect to any of the manufacturer
4 defendants or Teva regarding the manufacture of
5 generic opioids, right?

6 MR. RAFFERTY: Object to the form.

7 A. There is a section of the report
8 that talks about generic oxycodone of
9 Mallinckrodt. That is singled out at one
10 paragraph of the report.

11 Q. Okay.

12 A. But with that exception, the
13 report -- I think we're saying the same thing.

14 Q. Okay.

15 A. We're talking about the class of
16 opioids and recognize that generics are part of
17 that class of opioids.

18 Q. Fair enough. Thank you.

19 I also want to clarify, yesterday
20 it came up and then today you mentioned a
21 product that was formerly on the market that
22 was manufactured by Cephalon and a predecessor
23 of Cephalon and Teva, which is Oralet.

24 A. What was the name? It started with

1 an A, I believe. The manufacturer --

2 Q. Again, I don't have it at the tip
3 of my tongue.

4 A. The manufacturer started with an A,
5 if I remember. That was Oralet. It was a --

6 Q. Right.

7 A. It was the predecessor product --
8 maybe I'm using that word incorrectly, but the
9 predecessor product to Actiq. Same
10 formulation, I believe, essentially different
11 indication.

12 Q. Different dosing, different
13 indication, not at issue in this litigation,
14 right?

15 A. Oralet is not. I've asked. It is
16 not an indication -- it's not at issue in this
17 case, correct.

18 Q. And your opinions in your report,
19 which is Exhibit 1, contain no opinions about
20 Oralet or any action of Teva related to Oralet;
21 is that right?

22 A. That's exactly correct. The only
23 footnote if I could put there, ma'am, is that
24 it obviously was a part of my FDA experience

1 and my dealing with opioids and restricted
2 distribution.

3 So it may be a factual issue, but
4 no opinion with regard to the Oralet --
5 companies on Oralet not at issue here, other
6 than factually how -- I mean, how I handled
7 opioids.

8 Q. Your involvement factually and your
9 involvement recommending a limitation of no
10 marketing for Oralet, correct?

11 A. Correct.

12 Q. So --

13 A. Among other things.

14 Q. -- you give -- but you're not
15 opining that Oralet is a part of this case?

16 A. It is not, to my understanding.

17 Q. Your opinions related to Actiq and
18 Fentora appear to me in your report to be
19 limited in time. Is that right?

20 A. I would -- the way I would phrase
21 it, if this is helpful, I think they're limited
22 to two real issues. And to those issues, we
23 can decide what time frame. But one really is
24 off-label indication, and the second is failure

1 to comply with the risk maps.

2 So those are the two sort of
3 issues, and then we can discuss the conduct and
4 the evidence under those two time periods.

5 Q. So before we get to the substance,
6 let's talk first about Actiq or Actiq. It can
7 be pronounced either way, I think. I'll
8 probably say Actiq, but I think --

9 A. No, you're right. It's your
10 client, and I --

11 Q. So with respect to Actiq, you've
12 got two opinions; is that right? And feel free
13 to look at your report. The first one I see on
14 page 254, which is, you opine that Teva
15 marketed Actiq for non-malignant pain for which
16 safety had not been established by substantial
17 evidence.

18 A. That's a heading, and I believe
19 it's carried forward exactly -- maybe not
20 exactly in those words, but almost identical in
21 paragraph 474.

22 Q. Right. And 474 sort of summarizes
23 the paragraphs that precede it. And you
24 summarize in paragraph 474 of Exhibit 1, In my

1 opinion, Teva marketed Actiq for non-cancer
2 pain, an indication that lacks substantial
3 evidence to support safety.

4 Correct?

5 A. Exactly.

6 Q. So that's your first opinion about
7 Actiq, right?

8 A. Yes.

9 Q. The marketing materials that you
10 refer to in your report all pre-date -- or are
11 all dated 2006 or earlier; is that right?

12 A. I'll take your -- not to waste your
13 time, I think that is correct.

14 Q. Do you have any opinions regarding
15 the marketing of Actiq after 2006?

16 A. I'd have to go back and look at the
17 reliance list and look to answer your question
18 precisely, but you can base -- I mean, I think
19 it's fair to say that what's in the report and
20 the evidence in the report is what I will focus
21 on, unless there's something in the reliance
22 list that I've missed.

23 Q. Are you aware that Teva ceased
24 marketing of Actiq in 2006 when Fentora was

1 approved?

2 A. I think I do recall that.

3 Q. So does that help you confirm for
4 me that your marketing opinions relate to
5 marketing from 2006 or earlier?

6 A. I think that would be correct.

7 Q. At all times that Actiq was
8 marketed, it was identified and characterized
9 as a CII product; is that right?

10 A. Of course.

11 Q. At all times that Actiq was
12 marketed, it was subject to a risk management
13 program; is that right?

14 A. Yes. It would not have been
15 approved but for that.

16 Q. And your second opinion relates to
17 the risk management program -- your second
18 opinion related to Actiq. Is that right?

19 A. The second opinion --

20 Q. And we can see it just continuing
21 actually in your report.

22 A. Yes. I mean, I think that -- well,
23 I think that that deals with off-label
24 marketing in general, and the audits and the

1 requirements under that.

2 Q. And if I could direct your
3 attention, sir, please, to Exhibit 1, the
4 section --

5 A. Exhibit 1, my report.

6 Q. Which is your report, yes, sorry.
7 Sorry. I'm referring to it by the exhibit for
8 the record, but let's call it your report.

9 A. Sure.

10 Q. Your report, the opinion regarding
11 the marketing of Actiq begins in paragraph 475
12 and continues through paragraph 482, which is
13 on page 260.

14 A. That's the marketing as it failed
15 to comply with the risk management strategies.

16 Q. Right.

17 A. And what was done -- yes. And let
18 me know if you want me to pull those documents.

19 Q. Yeah, and if at any point you need
20 to refer to the document --

21 THE WITNESS: Gerard, can you just
22 give me the notebook kindly that begins
23 475 so I can have it and hold it,
24 please.

1 Q. So the risk management program that
2 you noted a moment ago is a part of the
3 approval process -- part of the approval for
4 Actiq, correct?

5 A. Yes, certainly that's correct.

6 Q. And understanding that you don't
7 have the -- any of the versions of the risk
8 management program in front of you, do you
9 recall whether that risk management -- strike
10 that.

11 Do you recall that the Actiq risk
12 management program required Teva to report
13 quarterly to the FDA about certain things?

14 A. There was surveillance and
15 monitoring to determine the effectiveness, I
16 mean, of -- and I think it's exactly to provide
17 a quarterly report to FDA compiled from all
18 data collected by the methods described under
19 the surveillance and monitoring programs and
20 intervention, and it will describe and provide
21 data on any concerns of off-label usage.

22 Q. As a part of rendering your
23 opinions regarding Teva's compliance with the
24 Actiq risk management program, did you review

1 all of the quarterly reports that were
2 submitted by it to the FDA?

3 A. I'm sitting here today, I'm -- to
4 be honest, I'm drawing a blank. I'd have to go
5 back and just review the quarterly -- well, I'd
6 have to go back and review that.

7 Q. You're not rendering an opinion
8 that Teva failed to comply with its quarterly
9 reporting obligations; is that right?

10 A. No. I think my opinion, if I can
11 be precise, it was contrary to the key -- the
12 marketing was contrary to the key messages in
13 the FDA-mandated risk map.

14 Q. Do you recall -- strike that.

15 Did you see in your review of
16 materials regarding Actiq any findings or
17 determinations by the FDA that Teva failed to
18 comply with the risk management program for
19 Actiq?

20 A. No. I'd have to go back and
21 obviously look at the enforcement action that
22 was -- I mean, I have it -- I'd have to go back
23 and do some more homework. I don't -- I don't
24 want to testify one way or the other on that.

1 I just don't know.

2 Q. You recall that the quarterly
3 reports that Teva submitted regarding Actiq
4 included reports of adverse events for
5 off-label use, right?

6 A. I believe I do have some
7 familiarity with that, yes.

8 Q. Is it your expectation that because
9 that was a part of the quarterly report, that
10 FDA understood that Actiq would be used in
11 off-label -- in an off-label manner?

12 A. I wouldn't say it that way.

13 Q. Is it your understanding because
14 there was an off-label component to the
15 quarterly report that the FDA understood that
16 there may be off-label use by physicians of
17 Actiq?

18 A. Yeah, I'm not sure that that's -- I
19 mean, I think FDA was concerned about off-label
20 from the beginning, independent of the
21 quarterly reports. That's my only point.

22 Q. And you're not aware of any
23 marketing that occurred of Actiq -- strike
24 that.

1 You're not aware of any marketing
2 that Teva did of Actiq after 2006, correct?

3 A. No. Exactly the evidence in my
4 report.

5 Q. Thank you. You are not issuing any
6 opinion in this litigation related to the
7 adequacy of the label for Actiq, are you?

8 A. Not -- not -- no. I think the
9 answer to that question would be no. I would
10 just want to reserve the ability to read the
11 label.

12 I mean, I issue no opinion on that.
13 We've discussed other inadequacies in general
14 in information. So there may be a sentence
15 here or there in the label that may be relevant
16 to our conversation, but I've issued no opinion
17 and will not issue an opinion that that label
18 was inadequate.

19 Q. In your opinion section of your
20 report regarding Actiq, you refer to internal
21 marketing documents, and we've -- you've
22 discussed at length with some of my
23 co-defendants your ability to kind of interpret
24 internal marketing plans.

1 Do you recall that testimony?

2 A. Yes.

3 Q. Have you reviewed and relied upon
4 any outward-facing external marketing documents
5 that you believe failed to comply with the
6 Actiq risk management obligation?

7 A. So I mean, I do have -- and I cite
8 it -- I do have certainly call notes that are
9 cited somewhere on reliance or not. Those are
10 outwardly facing. And I think that -- I mean,
11 they are pretty blatant when they come to
12 off-label marketing. So I think the call notes
13 are what come to mind --

14 Q. Did you --

15 A. -- right now.

16 Q. Did you review any marketing pieces
17 or leave-behinds related to Actiq that were --
18 that were used by either detail reps or anyone
19 at Teva that failed to comply with the risk
20 management profile?

21 A. No. What I was able to find --
22 what I was able to find and focusing on were
23 more the strategy documents, obviously the
24 documents that came out of the criminal -- what

1 of the enforcement action. And the actual
2 interactions between sales reps and doctors.

3 Q. And the enforcement action that
4 you're referring to, is that the 2008 plea
5 agreement and the corporate integrity agreement
6 in 2008?

7 A. Both, yes.

8 Q. Okay. And so we can agree that as
9 you testified a few moments ago, that the
10 actions that you are critical of related to
11 Actiq all pre-dated certainly the enforcement
12 action in 2008, but based on the documents
13 you've reviewed, were 2006 or earlier, correct?

14 A. I think that's -- that's fair.
15 Again, I think that would be fair.

16 Q. Do you know -- strike that.

17 Can you identify any physician in
18 Summit or Cuyahoga County who was misled by any
19 of the marketing of Actiq?

20 MR. RAFFERTY: Object to the form.

21 A. So sitting here today, I cannot
22 specifically. I would need to -- I mean, I've
23 searched the -- I have the call notes, and I'm
24 not sure -- I didn't search specifically for

1 Cuyahoga and Summit. I have dozens of call
2 notes here. But I would have to go search
3 these specifically for Cuyahoga and Summit and
4 would be happy to do that --

5 Q. And in --

6 A. -- in order to answer your
7 question.

8 Q. For purposes of your report, you
9 didn't identify any specific physicians who, in
10 2006 or earlier, were misled by any marketing
11 effort by Teva related to Actiq?

12 A. Well, I mean, we do -- we do have
13 call notes where this -- which do have
14 physician names and sales representative names,
15 and that those certainly show the drug is being
16 promoted for things like a migraine and low
17 back pain.

18 Q. But, sir --

19 A. And those have names associated,
20 and I can give you those names.

21 Q. Those notes are not notes from the
22 physicians demonstrating that they were misled
23 though, right?

24 A. You're correct, ma'am. Those are

1 notes from -- well, those are representations
2 by the sales rep.

3 Q. Can you identify any inappropriate
4 or improper prescriptions of Actiq that were
5 written in Cuyahoga or Summit County based on
6 any statements made by Teva?

7 A. Sitting here --

8 MR. RAFFERTY: Object to the form.

9 A. Sitting here right now, I cannot.
10 I would have to go back and -- I think the way
11 we would do this is, I would look at the call
12 notes specifically for Cuyahoga and Summit and
13 see what the representations are as we
14 discussed earlier, for example, of the doctors
15 in those call notes and whether they said they
16 would change. I don't have that evidence
17 today.

18 Q. And how would you identify from the
19 call note an improper prescription?

20 A. Well, when a call note as we saw
21 before says, discussed -- for example, it says,
22 discussed -- and I'm not saying this happened
23 in Teva, we'd have to look at the call notes,
24 but as I talked about earlier in certain call

1 notes, if it says, Discussed chronic back pain,
2 discussed migraine; doctor says, I'm going to
3 prescribe for this; doctor says he or she is
4 going to prescribe for this, again, that
5 doesn't tell you what the actual outcome is. I
6 understand that. But it takes you pretty
7 close, and we saw that earlier.

8 Q. Isn't it true --

9 A. Can I just add one point to that?
10 We do know -- we do have call notes outside of
11 Cuyahoga and Summit, and we do have testimony
12 that, in essence, what happened in Cuyahoga --
13 what happened nationally happened in Cuyahoga
14 and Summit.

15 Q. But right now you can't point me to
16 any improper prescriptions written in Summit or
17 Cuyahoga County as a result of alleged improper
18 marketing by Teva?

19 A. You're exactly correct. I'd have
20 to search these call notes for that.

21 Q. And isn't it true, sir, to
22 determine whether any prescription is improper,
23 you would have to look at the circumstances
24 surrounding that prescription, the information

1 in that patient's file, the interaction with
2 the physician, and actually talk with the
3 physician?

4 A. You're conflating something again.
5 It's late. Whether the promotion was off-label
6 and resulted in a prescription, I mean, that
7 you may or may not be able to determine from
8 the call note.

9 I mean, obviously if the call note
10 said, as we said, you know, discussed migraine
11 and chronic back pain, and doctor says, I'm
12 going to start prescribing for chronic back
13 pain and migraine in that call note --

14 Q. My question is different. My
15 question is not what the call notes show. My
16 question is whether you can determine that a
17 prescription is improper without looking at the
18 patient's medical history, the patient's
19 medical condition, and talking with the
20 physician about that physician's decision to
21 prescribe?

22 A. I'm sorry, I misunderstood.
23 With regard to improper
24 prescribing, I think you're correct. With

1 regard to improper promotion, I think -- and
2 its effect on promotion, you can determine that
3 from the documents.

4 Q. Sir, is it your opinion that any
5 prescriptions written before 2006 for Actiq
6 were improper?

7 A. All prescriptions for Actiq were
8 improper before 2006?

9 Q. Right.

10 A. Could you just give me the label
11 again? I mean, I'd like to see the label
12 before I answer that question.

13 Q. Well, it's actually a question that
14 I don't think you need to see the label. I
15 asked, is it your opinion that any
16 prescriptions written before 2006 -- so when
17 you opined that this improper marketing was
18 going on -- were any prescriptions written in
19 that time period improper?

20 A. I need to see the --

21 MR. RAFFERTY: Object to the form.

22 A. I need to see the label.

23 Q. Why do you need to see the label to
24 answer that?

1 A. Because I want to see precisely
2 what the limitations of use says, and that
3 could inform me on -- you used the word
4 "proper," and I just want to be precise.

5 So I'd want to -- in certain
6 instances, FDA --

7 Q. Well, I don't --

8 A. -- for example, in Oralet, the
9 predecessor, if you were using Oralet out of
10 the constraints that we set for Oralet, so I
11 just want to be precise and I just --

12 Q. Sir, respectfully, I don't have
13 time to show you the label right now. My
14 question is simple. Either yes or no, all of
15 them were improper or all of them were not.
16 And then we can go through and talk about the
17 categories of those which you have opined are
18 improper and those which are not.

19 MR. RAFFERTY: Okay. I'm going to
20 state an objection. I think there's
21 been some confusion, because I believe
22 you've used the words "any" and "all" at
23 different times, and so --

24 MS. FEINSTEIN: Thank you, Counsel.

1 MR. RAFFERTY: -- I think, and if I
2 could just -- two seconds -- and I think
3 it's not yes or no, and I don't think
4 it's appropriate to instruct the witness
5 on how to answer the question. It could
6 be that he can't answer the question
7 without reviewing the documents, which
8 he has a right to do.

9 MS. FEINSTEIN: Let me try again.

10 Q. So, sir, you've opined -- it's your
11 opinion that Teva engaged in improper marketing
12 of Actiq --

13 A. For off-label use.

14 Q. -- for off-label use before 2006,
15 right?

16 A. Correct.

17 Q. In that time frame, you would agree
18 with me that physicians could write off-label
19 prescriptions, right?

20 MR. RAFFERTY: Object to the form,
21 asked and answered.

22 A. Just give me one more second before
23 I answer that question.

24 Q. And if you can just tell us for the

1 record what you're referring to.

2 A. I'm looking at the various label
3 changes and the black box warnings. So I'm
4 just getting -- because unlike many drugs,
5 this, as I remember, has certain admonitions to
6 doctors. That's unusual. So there's an added
7 level of scrutiny here with regard to Actiq.

8 Q. And you're referring to the
9 schedule in your report that has sections --
10 excerpts of the label?

11 A. Yes.

12 Q. Okay.

13 A. So, for example, it says -- just so
14 you know why I want to be careful, it says,
15 Physicians and other health care providers must
16 become familiar with the important warnings in
17 this label.

18 Q. Right.

19 A. So that's -- it's very rare that
20 there's an admonition that says, Physicians
21 must become aware of that in a label.

22 Q. And so, sir, is it your opinion
23 that all prescriptions written off-label for
24 Actiq were improper?

1 MS. FEINSTEIN: Can we go off the
2 record while he's reviewing this? Let's
3 go off the record.

4 VIDEO OPERATOR: 2:52, we are off
5 the video record.

6 (A discussion was held off the
7 record.)

8 VIDEO OPERATOR: 2:53, we are on
9 the video record.

10 BY MS. FEINSTEIN:

11 Q. Can you answer my question now?

12 A. I don't want to -- my opinion, and
13 I don't want to give a legal opinion, so I'll
14 use a little L, you know, I don't think it is
15 unlawful or violative, and again, I don't want
16 to get -- for a physician to prescribe
17 off-label. There are two -- but there is a --

18 Q. Okay. Well, that answers my
19 question, sir, and we're really tight on time,
20 and I don't mean to cut you off.

21 A. I understand, but there are two
22 things in this label that are unique when it
23 says it's indicated only --

24 Q. Thank you.

1 A. -- and physicians must -- it would
2 go towards that question.

3 Q. Thank you. Thank you, and I don't
4 mean to rush you. We're just all very tight.

5 A. I understand.

6 Q. So I'd like to now move to Fentora
7 and your opinions about Fentora which follow --
8 there's just one opinion actually regarding
9 Fentora in your report. And it --

10 A. Just give me the paragraph, please.

11 Q. Sure. The opinions start in
12 paragraph 483, which is on 260, and continue to
13 493, which is on page 262 of Exhibit 1, which
14 is your report.

15 A. Right.

16 Q. And paragraph 493 reads, In my
17 opinion, Teva promoted Fentora for
18 non-malignant pain, which lacks substantial
19 evidence to support safety.

20 Correct?

21 A. Correct.

22 Q. It appears to me, based on the
23 materials --

24 A. Sorry, that -- you read that,

1 that's paragraph -- I'm blocking. What
2 paragraph did you just read?

3 Q. 493.

4 A. 493, I'm sorry. I just haven't
5 finished -- yes, ma'am.

6 Q. Sure. It appears to me from
7 looking at your report that the materials you
8 relied on in reaching that opinion relate to
9 actions from 2008 forward. Is that right?

10 A. You know, I'm looking at the 2005
11 marketing plan in front of me, so I'd have to
12 look at -- in fact, that's cited in here also
13 on 489, the 2005 marketing plan.

14 Q. So 2008, it appears to me that from
15 2008 -- I'm sorry, I misspoke.

16 2008 back, so anything from 2008 to
17 earlier is the activity that you're critical of
18 with respect to Fentora; is that right?

19 A. That's the evidence. That and
20 anything in my reliance list would support the
21 evidence to this, yes.

22 Q. Do you have any opinion that
23 Fentora was improperly marketed by Teva in 2009
24 or forward?

1 A. I think you can trust my sense
2 to -- what's in the report is the evidence that
3 I have. I'd want to double-check my reliance
4 list, but my guess is that it will be what's in
5 the report.

6 I also have a sheet in front of me
7 if you want to take a look. I don't think --
8 I'd have to check the dates of these documents,
9 but during that --

10 Q. I'm sorry. And that those are
11 internal documents, you referred to again some
12 internal marketing documents in the body of
13 your report, right?

14 A. Yes. So yes. Well, I mean, body
15 or reliance list. I apologize, I'm not sure.
16 They're on my list.

17 Q. The document that you are looking
18 at right now is in your big packet that we are
19 going to mark. These are your kind of working
20 set of materials, and it's clipped with a
21 binder clip, and we're going to mark that as an
22 exhibit following the deposition, right?

23 A. Fine.

24 Q. But that's what you're looking at,

1 for clarity?

2 A. Exactly. Take this report, take
3 this page, and I think you can feel comfortable
4 that that's the -- that's what supports my
5 opinion.

6 Q. Perfect. Thank you. That was
7 going to be my question, so I appreciate that.

8 Doctor, you're not aware of any
9 marketing statements made by Teva in Cuyahoga
10 or Summit County, specific marketing statements
11 that were false or misleading, are you?

12 MR. RAFFERTY: Object to the form.

13 A. I think the answer to that would be
14 no, but the campaigns and the testimony is
15 there was -- this was national in scope on
16 break-through pain. So there's no reason to
17 think that -- or there's no evidence to say it
18 was any different there.

19 Q. And sitting here today, Doctor,
20 same question that I asked you a few moments
21 ago regarding Actiq, can you identify any
22 providers in Cuyahoga or Summit County who were
23 misled by any statements by Teva related to
24 Fentora?

1 MR. RAFFERTY: Object to the form.

2 A. Sitting here right now, I cannot.

3 Q. Can you identify any inappropriate
4 or improper prescriptions of Fentora that were
5 written in Cuyahoga or Summit County based on
6 false statements made by Teva?

7 MR. RAFFERTY: Object to the form.

8 A. I do have -- you can look at these
9 documents, and these are based on recall of
10 messages, and we'd have to dig down and see
11 where exactly these -- this recall was done in
12 this document to answer your question fully.

13 Because this clearly tells you what
14 the impact the recall was of those messages
15 that were off-label, and we see that -- again,
16 I think this was done nationally, and we'd have
17 to look -- again, this was nationally marketed.
18 So I'd just have to look -- we'd have to look
19 at the calls that were made.

20 Q. You can't identify any
21 inappropriate or improper prescriptions,
22 sitting here today right now, that were written
23 for Fentora in Cuyahoga or Summit County based
24 on false statements made by Teva?

1 MR. RAFFERTY: Object to the form.

2 A. You're talking about the
3 prescriptions itself --

4 Q. Yeah.

5 A. -- or the calls itself?

6 Q. The prescriptions.

7 A. Of Fentora? No, I cannot. I can
8 talk about -- I mean, I can talk about overall
9 physician national recall. That's all I can
10 do.

11 Q. Your report also refers to certain
12 funding provided by Teva to a couple of
13 organizations.

14 A. Do me a favor. Can I just get -- I
15 just need to switch my documents out. Do you
16 want to go off the record for a second?

17 MS. FEINSTEIN: Sure.

18 THE WITNESS: Just go off the
19 record. Preserve your time.

20 VIDEO OPERATOR: 2:59, we are off
21 the video record.

22 (A discussion was held off the
23 record.)

24 VIDEO OPERATOR: 3:02, we are on

1 the video record.

2 BY MS. FEINSTEIN:

3 Q. Doctor, I'd like to refer you to
4 paragraph 582.4 of your report, which is
5 Exhibit 1.

6 That paragraph refers to payments
7 made by Teva to the American --

8 A. 582 point --

9 Q. 4.

10 A. Yes.

11 Q. -- payments made by Teva to the
12 American Pain Society over the time period 2009
13 to 2013 --

14 A. Correct.

15 Q. -- in the amount of \$218,000,
16 correct?

17 A. Correct.

18 Q. Is it your opinion, sir, that those
19 payments were inappropriate or improper?

20 A. I think they contributed to the
21 overall view of opioids. I don't think that
22 they were illegal, but I think they contributed
23 to the overview of opioids.

24 Q. Do you know whether any of those

1 payments were made as a part of any risk
2 management obligations on the part of the
3 company?

4 A. I need to open my notebook, and I
5 don't want to do that under the time
6 constraints.

7 So I'd be happy -- so the answer
8 is, sitting here, I'd have to check that
9 question.

10 Q. If payments were made as a part of
11 a risk management program, would that change
12 your view of whether those were appropriate
13 payments or not?

14 A. Not if the risk management program
15 was misleading. And as we know from the
16 record, risk management programs did talk about
17 pseudoaddiction or less addictive risk. So
18 that, again, contributed to this change in
19 culture, so that's part of the problem.

20 Q. Referring you now to paragraph
21 610.3 of your report --

22 A. Is there rule that once we get to
23 the 600s, we can't go backwards?

24 Q. No, unfortunately.

1 So this paragraph refers to a
2 contribution by Teva in the amount of \$130,000
3 to the Federation of State Medical Boards.

4 Do you see that?

5 A. Yes.

6 Q. And you referred to this as a grant
7 to support the distribution of responsible
8 opioid prescribing, correct?

9 A. Yes.

10 Q. Is it your opinion, sir, that that
11 payment was improper?

12 A. I don't think it's illegal, but I
13 think if you go to paragraph 611, you see that
14 those statements that came out of that
15 organization were misleading.

16 So I wouldn't want to say that
17 money was illegal, but it did contribute to
18 that change in understanding of opioids, which
19 was misleading.

20 Q. But the payment itself was not
21 improper?

22 A. Well, I used the word "illegal." I
23 mean, I think it -- it certainly -- it would
24 have been better not to contribute to these

1 organizations that misled the public.

2 Q. And you didn't review any of the
3 underlying agreements or contracts related to
4 either of those payments with Teva and those
5 organizations, right?

6 A. I may have. I have to go back and
7 look at the reliance list.

8 Q. Sir, just a couple of other quick
9 questions, and then I've got to pass the baton.

10 You are not providing -- strike
11 that.

12 You're aware of the TIRF REMS
13 program?

14 A. Yes.

15 Q. You know that that program applies
16 to Fentora and Actiq, right?

17 A. Absolutely.

18 And a lot of controversy about that
19 program.

20 Q. Are you -- you're not rendering any
21 opinion in this litigation about TIRF REMS, are
22 you?

23 A. Other than they are inadequate. I
24 think you can stop there.

1 Q. You have not provided any opinion
2 regarding Teva's compliance with TIRF REMS,
3 have you?

4 A. Only what's -- only within the
5 report. They're certainly inadequate to do the
6 job. I think that would be my only --

7 Q. It's your view that the TIRF REMS
8 program is inadequate to do its job; is that
9 right?

10 A. I think the record is pretty clear
11 on that and the recent advisory committees and
12 testimony.

13 Q. But you don't have an opinion in
14 your report, Exhibit 1, about TIRF REMS and
15 Teva's products?

16 A. You asked me a question, and I gave
17 you an answer. I mean, I -- but I -- I mean,
18 that's why I answered it. But I'm not going to
19 disagree with you. I mean -- I mean, what's in
20 the report is in the report.

21 Q. Sir, are there any opinions that
22 you hold regarding Teva that are not in your
23 report but that you plan to testify about at
24 trial?

1 A. I would only -- anything -- if you
2 can change your question to include anything in
3 the report and what we just discussed today, I
4 would say I have no intent to go beyond what we
5 talked about today and what's in the report.

6 MS. FEINSTEIN: Excellent. Thank
7 you, sir.

8 With that, I am just going to note
9 on the record -- I am going to pass the
10 witness, but I will note on the record
11 Teva's objection to the amount of time
12 that all defendants collectively were
13 allowed to conduct this deposition
14 that -- regarding an expert who rendered
15 extensive opinions about many companies,
16 and sharing this limited time is
17 inadequate, from our opinion.

18 So with that, thank you, Doctor.
19 Appreciate it, and we'll go off the
20 record.

21 MR. RAFFERTY: Wait, wait.

22 Plaintiffs continue to disagree.

23 VIDEO OPERATOR: 3:08, we are off
24 the video record.

1 (Recess from 3:08 p.m. until
2 3:25 p.m.)

3 (Exhibits Kessler-25 through
4 Kessler-39 marked for identification and
5 attached to the transcript.)

6 VIDEO OPERATOR: 3:25, we are on
7 the video record.

8 EXAMINATION

9 BY MS. LEVY:

10 Q. Good afternoon, Dr. Kessler. My
11 name is Jennifer Levy, and I am counsel for the
12 Allergan defendants in this case. I appreciate
13 your patience in hanging with all of us over
14 this two-day period. I really do.

15 I would like to pick up with
16 where -- the questioning just before the break
17 that counsel for Teva had asked you with
18 respect to your opinions on what prescriptions
19 were tainted by unlawful marketing and what
20 prescriptions weren't, and I would like to ask
21 you specifically with respect to the opioid
22 Kadian.

23 If I represent to you, Dr. Kessler,
24 that there were 14,908 Kadian prescriptions in

1 Cuyahoga and Summit County over the period of
2 time that that product has been on my client's
3 watch, you would agree with me that some
4 portion of those prescriptions were legitimate
5 prescriptions for patients who needed the
6 product, correct?

7 A. I think that would be fair.

8 Q. And in your view, to the extent
9 there were any physicians that prescribed some
10 of those 14,908 prescriptions who were misled
11 by improper marketing, those prescriptions
12 would not be appropriate prescriptions, in your
13 view; is that correct?

14 A. If they were misled -- and we had,
15 you know, an extended back-and-forth; is there
16 any possibility that they would be still
17 appropriate, because they weren't misled. But
18 once they were misled, it comes pretty close.

19 So I think that's a fair -- we had
20 this discussion a little while earlier, and I
21 stand by that, I think is probably the best way
22 to say it.

23 Q. It's possible -- it's possible, I
24 suppose, for a prescriber to be misled for a

1 period of time and then unmisled. Do you agree
2 that that's a possibility?

3 A. Yeah, that's -- in essence, those
4 are the kinds of things that I was referring
5 to.

6 Q. Okay.

7 A. That was --

8 Q. So in order to tell --
9 I'm sorry. I did not mean to cut
10 you off.

11 In order to tell if a prescription
12 in a particular jurisdiction is legitimate, you
13 would need to know if the prescriber was misled
14 or if the prescriber wasn't misled, right?

15 MR. RAFFERTY: Object to the form.

16 A. I think there's a number of
17 methodologies that I talked about over the last
18 day and a half that --

19 If there's an ROI that has been
20 calculated on certain promotional activities
21 and you know those promotional activities had
22 misleading -- and you know what increased
23 number of prescriptions that promotional
24 activity led to, I think that's one methodology

1 that we talked about.

2 Obviously, there are others, as
3 you're alluding to.

4 Q. I think I understand you to say, if
5 there is evidence that a particular misleading
6 promotional activity is linked directly to an
7 increase in prescribing, you can assume that
8 that increase is -- results in prescriptions
9 that are not legitimate and lawful. Correct?

10 A. "Lawful" -- take "lawful" out
11 because -- but it would be inappropriate -- it
12 would be -- it would be a contribution of
13 inappropriate prescribing.

14 Q. Okay. And you haven't made any
15 attempt to quantify for the opioid Kadian what
16 percentage of the prescriptions in Cuyahoga and
17 Summit County were lawful versus unlawful or
18 legitimate versus illegitimate? You haven't
19 made an attempt to do that, have you?

20 MR. RAFFERTY: Object to the form.

21 A. Correct.

22 Q. And you haven't made an attempt to
23 do that for any of the opioids that are the
24 subject of your report. You haven't made an

1 attempt to quantify percentages of -- what
2 percent were legitimate prescriptions and what
3 percent weren't. That's not -- you haven't
4 done any of that, have you?

5 A. I've not done --

6 MR. RAFFERTY: Object to the form.

7 A. I don't think that's exactly my
8 testimony here over the last day and a half. I
9 think there were documents -- happy to pull
10 them, again -- that show what the ROI was with
11 regard to other manufacturers. I don't see
12 that with regard to documents I've seen in
13 Kadian. I don't have those ROI documents that
14 I'm aware of from Kadian.

15 Q. And your report addresses Actavis
16 and Kadian on pages 263 through 276; is that
17 right?

18 A. Yes.

19 Q. Okay. And are those the only
20 opinions that you intend to offer in the trial
21 of this case with respect to Actavis?

22 A. If you stopped right now and you
23 passed the baton, the answer to that question
24 would be yes.

1 If you ask me other questions, you
2 know, I may give you certain opinions based on
3 what you ask me. But my intent right now would
4 be to stop right here.

5 Q. Okay. That's fair.

6 So if I'm understanding you
7 correctly, the opinions in that section of your
8 report plus whatever we talk about today are
9 the opinions that you intend to give at trial
10 with respect to Actavis; is that right?

11 A. Well said, Counselor.

12 Q. And I take it, by extension, that
13 you don't intend to offer any opinions with
14 respect to products that Actavis may have
15 marketed or sold that are not addressed in your
16 report; is that correct?

17 A. So the only -- the only caveat to
18 that, Counselor, is one that I think I made
19 early in the day twice, both to Mallinckrodt
20 and I believe to Teva, is, we know Actavis
21 sold -- its predecessors sold oxycodone ER for
22 a period of time in a generic form, I believe,
23 and to the extent that the general statement
24 about the manufacturers contributing to

1 increasing that water level, as I testified,
2 would apply to both the generics and the brand.

3 Q. So let's talk -- I'm going to
4 place-hold that to talk more about in a moment.

5 But with that exception, other than
6 that exception, you don't have any other
7 products or opinions aside from what we talk
8 about today that you intend to testify about at
9 trial; is that correct?

10 A. Correct.

11 Q. Okay. Now, let's do some marking.
12 We put a sticker on your pile in front of you.
13 And can you do me a favor and tell me what
14 exhibit number that is.

15 A. 36, ma'am.

16 Q. What is Exhibit 36?

17 A. 36 was simply, I asked -- what
18 this -- what this whole thing is?

19 Q. Yes.

20 A. Sort of my brain on paper.

21 Q. So let me see if you would agree
22 with my characterization.

23 Is this your file as it relates to
24 Actavis?

1 A. Well, there's binders. There's
2 bigger sheets than even these. There's -- so
3 there's a number of different things here. But
4 I am -- if you'll -- it's not the entire file,
5 but I think maybe it's -- it represents
6 documents that I've cut and pasted or notes or
7 markings that I have made over a period of time
8 and inartfully -- and tried to tape onto paper
9 or write onto paper.

10 Q. Give me just one minute.

11 Okay, Dr. Kessler. Exhibit 36,
12 which looks to me to be your notes and some
13 important documents that you've pulled out in
14 your opinion with respect to Actavis.

15 Is that a fair characterization?

16 A. Yes, ma'am.

17 Q. Okay. In addition to that, you
18 have another extremely large document in front
19 of you that is marked Exhibit what?

20 A. 39.

21 Q. What is Exhibit 39?

22 A. So 39 is just a visual, in essence,
23 of the paragraphs in my report that I attempted
24 to put together by categories.

1 So it talks about low abuse
2 potential, less addiction, pseudoaddiction,
3 overstatement of benefits, overstatement of
4 other benefits. So it uses those headings as
5 they apply to all the manufacturers, and then
6 these are just simply the paragraphs under the
7 report under those headings.

8 So it's an attempt to see things
9 visually that I may not -- all in one sheet
10 that just -- you know, it's just a visual
11 mapping.

12 Q. It's how you organize the evidence
13 that you've found for particular defendants?

14 A. It was a way of looking -- trying
15 to understand -- trying to see things in
16 just -- see things in a little different -- in
17 different categories.

18 Q. In addition to 36 and 39, I have in
19 front of me two binders that are labeled
20 Number 9, Actavis, both of them, and they have
21 different paragraph numbers. We've marked
22 these as Exhibit 37 and 38.

23 Are you familiar with these?

24 A. I'm very familiar with those.

1 Q. These are the documents in your
2 reliance materials that relate to Actavis,
3 correct?

4 A. No.

5 Q. What are these?

6 A. So those are the documents that are
7 cited in -- so if you turn to a paragraph,
8 you'll see a paragraph number, and that
9 corresponds to this paragraph. And if there's
10 a footnote, it is a cite from that paragraph,
11 that cite would be in that paragraph. And if
12 there's a quote, that's what the flags are that
13 you see sticking out are the quotes.

14 But that doesn't necessarily --
15 these don't print out everything on the
16 reliance list.

17 Q. So this is an appendix,
18 essentially, to your report, everything cited
19 in your report?

20 A. I've given you an appendix. I've
21 given you schedules. I would hate to call it
22 an appendix because I hope I don't have to
23 carry these around for the rest of my life. So
24 I wouldn't give them any more official status

1 other than wanting to have these documents
2 available.

3 As you saw me earlier, people asked
4 me about a question about a paragraph, and I
5 wanted not to just to read my report, but
6 wanted to see the document that was cited in
7 that. So I opened those binders. That's the
8 purpose.

9 Q. If I wanted to know the entire
10 universe of your reliance materials that relate
11 to Actavis, I would need to have the documents
12 that are in the big chart that is marked as
13 Exhibit 39, the pile in front of you that's
14 marked as Exhibit 36, these two documents, 37
15 and 38, and what else?

16 MR. RAFFERTY: Object to the form.
17 Go ahead. I won't interfere.

18 A. You would need to take the reliance
19 list, create PDFs of the reliance -- have PDFs
20 of the reliance list and -- what was your
21 question? With regard to Actavis? Is that
22 what you specifically -- you would probably
23 have to search the reliance list in addition to
24 these documents.

1 Q. And did you read everything in all
2 of these binders?

3 A. I'm not going to -- I don't mean to
4 be facetious. Define "read."

5 Q. Lay your eyes on it, just lay your
6 eyes on everything in the binders, just start
7 with that.

8 A. I laid my eyes on a lot of things,
9 yes. I'm not sure that I've studied every -- I
10 certainly have not studied every page, but I
11 certainly have laid my eyes on a lot of these
12 pages, but I don't want to represent that every
13 page got the same kind of -- every word got
14 read.

15 Q. Okay. I want to talk to you more
16 about those documents, but for a minute, I want
17 to go back to your report and start with
18 something I read in paragraph 6 where you
19 state, I am a senior advisor to TPG Capital, a
20 leading global private equity firm which owns
21 pharmaceutical and biomedical companies.

22 Do you recall that in your report?

23 A. Yes, ma'am.

24 Q. Are you paid by TPG to be a senior

1 advisor?

2 A. Yes.

3 Q. How are you paid?

4 A. Well, really two ways. I think
5 there's some retainer that's relatively small,
6 and then there are TPG companies that I sit on
7 the boards of. And those companies -- by
8 sitting on the boards, I'm paid by those
9 companies.

10 Q. Do you have stock in TPG?

11 A. No.

12 Q. And do you have stock in any of the
13 companies in TPG?

14 A. I have stock in the companies that
15 are owned, yes. I believe that's correct.
16 Those are privately held shares.

17 Q. Okay. One of the companies that
18 TPG owns is Collegium; is that correct?

19 A. Not a company that I've worked on.

20 Q. You don't know, one way or the
21 other, whether --

22 A. Sorry. I don't --

23 Q. -- TPG owns Collegium?

24 A. I know the ones I've worked on. I

1 don't know that.

2 Q. I'm not asking if you've worked on
3 it. I just want to know if you know whether
4 TPG owns Collegium.

5 A. I don't.

6 (Exhibit Kessler-40 marked for
7 identification and attached to the
8 transcript.)

9 BY MS. LEVY:

10 Q. I'm going to show you what I've
11 just marked as Kessler Exhibit 40.

12 I'll ask you, Dr. Kessler, if
13 you've seen this document before or are
14 familiar with its contents.

15 A. Sitting here today, I have no
16 recollection of this. I don't -- I don't
17 believe I've seen this document.

18 Q. Okay. No one's ever told you that
19 Collegium Pharmaceuticals received this warning
20 letter from the FDA?

21 A. No. I'm not involved. Absolutely
22 not.

23 Q. That's new news to you?

24 A. Absolutely. I'm not involved.

1 Never seen this before.

2 Q. Does the fact that a company gets a
3 warning letter, does that automatically mean
4 the company has done something wrong?

5 A. Pretty much. I mean -- well, let's
6 look at the warning letter.

7 Q. Before we look at that one, I mean,
8 in general. If you know a company got a
9 warning letter, can you be sure that it did
10 something wrong, in your opinion?

11 A. Ma'am --

12 MR. RAFFERTY: Object to the form.

13 A. As you know, there's warning
14 letters, and there's warning letters. And I
15 would want to -- there are warning letters that
16 say that there's -- FDA considers it a
17 violation of the act and will cite a specific
18 statutory section, and that -- so that, I
19 think, gives you -- depends what the letter
20 says is the answer.

21 Q. Fair point.

22 I bet you will agree with me that
23 the FDA keeps enforcement statistics on its
24 website.

1 You're familiar with that, right?

2 A. I am.

3 Q. And, in fact, you can click on the
4 FDA website and see summaries by year of those
5 FDA statistics, correct?

6 A. Yeah.

7 (Exhibit Kessler-41 marked for
8 identification and attached to the
9 transcript.)

10 BY MS. LEVY:

11 Q. I'm going to show you what's been
12 marked as Kessler Exhibit 41.

13 I will represent to you,
14 Dr. Kessler, that this is a chart that we
15 copied from the FDA website or pulled
16 substantively from the FDA website.

17 Are you familiar with statistics
18 that look like this from the FDA website?

19 A. In general, yes.

20 Q. Under the Kessler FDA, were
21 statistics like this kept?

22 A. I assume so. I can't visualize
23 them, as I sit here. But I think that's fair.
24 I think it's a practice that goes back decades.

1 Q. The left-hand column of Exhibit 41
2 says Enforcement Type, and the right-hand
3 column says Count.

4 Do you see that?

5 A. I do.

6 Q. I will represent to you that we
7 pulled Exhibit 41 for 2017.

8 Will you agree with me,
9 Dr. Kessler, that the actions on the left-hand
10 side under Enforcement Type, these are actions
11 that the FDA can take or cause to be taken
12 directly or indirectly, correct?

13 A. I assume you're referring to
14 injunctions and going into court, et cetera.
15 Is that what you mean by "indirectly"?

16 Q. Mm-hmm.

17 A. Yeah. I think if we understand
18 that, I think that's -- there are steps to
19 each -- different steps to each one of these.
20 Some of these, for example, recalled are --
21 they may be voluntary recalls. So be careful
22 on whether FDA took that step or the
23 manufacturer took that step. So there's
24 nuances to these.

1 Q. And that's why I said "directly or
2 indirectly."

3 These are things that can happen
4 when the FDA sees a problem, right?

5 A. Or when a manufacturer sees a
6 problem, they can do a recall. I'm not sure we
7 would say that all recall products are -- I
8 mean, they get reported ultimately -- should
9 get reported to the FDA. The manufacturer may
10 see them first.

11 Q. Assuming that I represent to you
12 that I copied these correctly from the FDA
13 website, you understand the count on the
14 right-hand side to be the number of times that
15 the FDA took such an action in 2017? Is that
16 how you would read that?

17 MR. RAFFERTY: I'm going to object
18 just because I don't know where -- I
19 haven't had a chance to corroborate
20 where it came from. So I'm just going
21 to object since there's no FDA cite or
22 anything --

23 MS. LEVY: Sure. That's exactly
24 why I asked the question the way I did.

1 A. You're asking me -- I'm sorry. The
2 question was --

3 Q. What does the count mean on the
4 right-hand side?

5 A. I would think the number of actions
6 under each. It's a lot of warning letters, but
7 I'm not -- you know, I'm sure you took it off
8 right. 15,000 warning letters seems like a lot
9 of warning letters in one year.

10 I'm not sure -- I'm sure you did
11 this accurately, and I'll take any
12 representations you make, Counselor.

13 Q. In your own experience, warning
14 letters are a common thing that the FDA does,
15 correct?

16 A. Common, you know, I mean, they
17 are -- they are something that the FDA does.

18 Q. Okay. And recalled products are
19 also common. Here we see in 2017, there's --
20 9,199 is the count for recalled products, and
21 2,945 is recall events.

22 Do you see that?

23 A. Yeah. Yes, I see this.

24 Q. It's not uncommon to have recalled

1 products and recall events, is it?

2 MR. RAFFERTY: Object to the form
3 in terms of not defining what "products"
4 or "events" are.

5 Q. You can answer.

6 A. I would phrase it, it's not
7 unusual. You've got to look at the denominator
8 to see what's common here. It's not unusual to
9 see recalled products.

10 MR. RAFFERTY: What exhibit was
11 that?

12 THE WITNESS: 41.

13 Q. I have in front of you -- I think I
14 marked the Collegium warning letter at -- as
15 Exhibit 40.

16 Can you pull that one back up.

17 A. Yeah.

18 Q. Is Collegium a drug company that
19 you believe has contributed to the opioid
20 crisis?

21 A. I have not, you know -- there may
22 be one or two issues over, I don't know, the
23 last -- since 2008 that -- where I may have
24 discussed with colleagues ADT formulation or

1 something like that, as I think I talked about
2 earlier.

3 But save for that, I have no --
4 I've not studied Collegium. I'm happy to do
5 that, if you'd like. I just -- I have -- but
6 for those two conversations, really one on
7 ADT -- the one conversation I remember on an
8 ADT product, I have no knowledge of anything
9 about this. I don't know who Mr. West is. I'm
10 just not involved with it.

11 Q. For purposes of this litigation,
12 you have not been asked to study Collegium's
13 responsibility, have you?

14 A. It was not one of the
15 manufacturers -- is it a defendant? I
16 wasn't -- maybe it's on my list. I don't know
17 if it's on my list. I listed all the
18 defendants. It's in my report.

19 But I was asked specifically to --
20 by plaintiffs -- they gave they the scope.
21 They gave me the list. I didn't change that in
22 any way.

23 Q. Got it.

24 So what you did for purposes of

1 this litigation was to study the defendants
2 that are the subject of your report, and that's
3 it?

4 A. If you look at the beginning of the
5 report in the first section, I think the last
6 several paragraphs or paragraph on just scope,
7 I asked specifically for what the scope was,
8 and I addressed myself, after it was determined
9 what the scope was, to those question.

10 Q. Did you make any effort to
11 determine how many other drug companies had
12 conduct that contributed to the concerns you
13 have about opioids?

14 MR. RAFFERTY: Object to the form.

15 A. I will tell you that I was sort of
16 exhausted after just doing these, to be honest,
17 right. I mean, this is -- the scope that was
18 given to me is vast.

19 I will tell you that in -- I mean,
20 I did study the database broadly.

21 Q. What database?

22 A. Well, the production database.

23 Okay.

24 Q. By "the production database," you

1 mean the documents produced in this case?

2 A. Yes.

3 Q. By these defendants?

4 A. Well, again, there were third
5 parties, et cetera. I mean, don't ask me to
6 define -- I mean, the database are the
7 defendants.

8 So I did look at that -- that sort
9 of broadly. But there are other drugs that we
10 talked about earlier where I didn't spend a lot
11 of time because they were not the subject.

12 I mean, my impression and my sense
13 was that the major drugs that contributed to
14 the epidemic were drugs that are identified in
15 the report. That was my impression, and that's
16 my sense.

17 Q. But you didn't do anything to see
18 if that was true? You didn't look at any other
19 drug companies other than the ones that are in
20 the seven in your report? You didn't
21 look at -- I'm sorry -- the six in your report?

22 MR. RAFFERTY: Object to the form.

23 Q. You either did or you didn't. You
24 examined the six in your report, and you

1 studied those until you were complete with
2 that?

3 A. I did.

4 Q. But did you study any others --

5 A. Yes, I did.

6 Q. -- other than the six?

7 MR. RAFFERTY: Object to the form.

8 Q. Just name -- without going into
9 what you did, name the other drug companies
10 that you studied.

11 A. Abbott.

12 Q. Who else besides Abbott did you
13 study?

14 A. Abbott's the one that comes to
15 mind.

16 Q. Is that the only one?

17 A. I'd have to go back and look.
18 That's the one that comes to mind.

19 Q. When you studied Abbott's conduct,
20 did you conclude that Abbott had responsibility
21 for the opioid crisis?

22 A. I think so.

23 Q. Okay.

24 A. I mean, it -- so the record is

1 clear, I mean, it was basically -- it
2 co-promoted oxycodone with Purdue. So there
3 was a joint licensing agreement. So I think
4 it's fair to say that those marketing plans of
5 Purdue carried over to Abbott. It was a joint
6 venture of sorts.

7 Q. Now, you mentioned, I believe,
8 earlier that you did not study Collegium,
9 right?

10 A. No. I'm not sure that -- no, the
11 answer is, I did not.

12 Q. Okay. And as you sit here today,
13 do you have an opinion on whether Collegium
14 contributed to the opioid crisis?

15 MR. RAFFERTY: Object to the form.

16 Q. It's a yes, no, or I don't know.

17 A. I haven't studied it. So I can
18 tell you I have no opinion.

19 Q. Okay. And how many total drug
20 manufacturers are there that manufactured and
21 marketed opioids in this country?

22 A. I have documents on market share
23 that I'd be happy --

24 Q. Roughly. What's the rough number

1 of companies?

2 A. I'd want to look at the charts that
3 I have before I give you an answer.

4 Q. Do you know if it's dozens?

5 A. I have -- I have the market share.
6 There are -- I wouldn't want to hazard a guess
7 at this time. I do have the documents. If you
8 want me to look at them, I'd be happy to give
9 you the numbers.

10 Q. We may want to do that, but for the
11 moment, you'll agree with me that there are
12 many, many drug manufacturers that you did not
13 study to determine whether they had
14 responsibility for the opioid crisis. Is that
15 fair?

16 MR. RAFFERTY: Object to the form.

17 A. No. I think it's fair to say that
18 I studied the major -- without a doubt, the
19 major brand name companies.

20 Q. And how did you determine the major
21 brand name companies, or did you just study
22 what you were asked to study by counsel?

23 A. No. If you look at those market
24 shares and you look at certainly the extended

1 release and you look at the competitors, it's
2 very easy -- when you look at Purdue's market
3 plans, they talk about who the competitors are.
4 I showed, for example, the Mallinckrodt graph
5 yesterday that showed the Purdue market share.

6 So you can quite easily, based on
7 the record, see what the percent market shares
8 are and who's competing against whom. Purdue
9 was competing against Kadian early on. You see
10 that in the documents.

11 Q. Are you finished?

12 MS. FREIWALD: Objection, move to
13 strike. It mischaracterizes the facts
14 in this case.

15 BY MS. LEVY:

16 Q. I'm going to ask a pretty simple
17 question.

18 You've identified six manufacturers
19 in your report, and today you've identified
20 Abbott.

21 Is there any other drug company
22 whose conduct you studied to determine if they
23 had contribution for the opioid crisis? Any
24 others other than those seven?

1 A. Yes.

2 Q. What other company?

3 A. Well, I think I talked about --
4 well, I talked about Rhodes.

5 Q. Okay. And did you conclude that
6 Rhodes does or does not have responsibility for
7 the opioid crisis?

8 A. I think Rhodes is owned by Purdue.
9 I think the answer is complicated.

10 Q. You can't say one way or the other?

11 MR. RAFFERTY: Object to the form.

12 A. Well, Rhodes is -- Rhodes, at
13 different times, is making API. Noramco is
14 making bulk. Tasmanian Alkaloids. I've
15 studied all those.

16 They certainly feed in, right, to
17 the -- without Tasmanian Alkaloids, but for,
18 you wouldn't have supply the way we had supply.

19 So again, I think it's fair to say
20 it's complicated, and I studied those, yes.

21 Q. Let's talk about drug companies
22 that have no affiliation with any defendant in
23 this room.

24 How many of those did you study,

1 aside from Abbott, to determine if they had
2 contribution for the opioid crisis? Just a
3 number. How many?

4 A. I studied -- well, there's Abbott.

5 Q. Just a number.

6 A. Without any affiliation?

7 Q. Without affiliation to these
8 defendants.

9 A. So Abbott has an affiliation -- I
10 just want to understand your question -- to
11 Purdue. Is that your question?

12 Q. Without any affiliation, is my
13 question.

14 Let me redo the question --

15 A. How are you defining "affiliation"?

16 Q. -- just so we're clear.

17 MR. RAFFERTY: He can ask an
18 explanation of the question if he
19 doesn't understand it, Counsel, and
20 that's what he was doing.

21 Q. Here's the question. How many drug
22 companies with no affiliation to defendants in
23 this room did you study aside from Abbott to
24 determine if they had contribution for the

1 opioid crisis? How many? Just the number.

2 A. So I've looked at data -- for
3 example, for Amneal, Mylan, Qualitest, Roxane,
4 Sandoz, Watson -- which, I guess, is, you know,
5 related to you, so I take that back --
6 Rhodes -- when you look at the contributions on
7 the generic side.

8 So, I mean, I've looked at -- I've
9 looked at the market share and how those are
10 spread out, and I've tried to study somewhat
11 the flow between -- from the raw materials in
12 the poppy fields to the API manufacturer to the
13 brand to the generics.

14 This is all very highly
15 interconnected, because, I mean, for example,
16 Rhodes is on my list, but Rhodes -- rather,
17 Watson, are connected to you.

18 So I think that the fact is, I am
19 very comfortable that the manufacturers
20 identified in the report did the bulk of the --
21 the vast, vast, vast majority of the promotion.

22 And I think it's basically shown
23 when you look at the competitive landscape and
24 the documents, again, in the record. The

1 competitive landscape is such that the
2 defendants that were identified make me
3 comfortable that it's the bulk of the promotion
4 that is happening.

5 Q. So those other drug companies that
6 you just named are not responsible in any way
7 for the opioid situation we're in? Is that
8 your -- are they responsible or not
9 responsible? Which is it?

10 MR. RAFFERTY: Object to the form.

11 A. So --

12 Q. I'd like to ask you, before you
13 answer, to give me a short answer to this
14 question.

15 The drug companies you referenced
16 in your last answer, are they -- do they have
17 responsibility, have no responsibility, or
18 somewhere in between?

19 MR. RAFFERTY: If you can --

20 Q. I don't need an explanation.

21 MR. RAFFERTY: If you can answer
22 the question the way she's directing you
23 to, which is inappropriate -- if you can
24 answer it, then you can answer it. But

1 you don't need to be instructed to what
2 your options are.

3 A. I don't see the record -- I mean,
4 in the record, in what I've looked, I don't see
5 the extent of the change in medical practice by
6 these companies that were effected by the
7 evidence in this report.

8 Q. And you -- I think in your last
9 answer, you said, "the vast, vast, vast
10 majority of promotion" was done by the
11 defendants in this case.

12 Have you studied the quantity of
13 promotion? Have you studied the number or
14 the -- number of details or the quantity of
15 promotion?

16 A. Oh, yeah. I mean, I have looked at
17 sales force volumes. I have looked at, I mean,
18 a whole lot of statistics. There's a
19 Schedule, I think, 8 that has the promotional
20 details. So I have looked at that, yes.

21 Q. And what percentage of promotion is
22 the vast, vast majority? What percentage is
23 that?

24 A. I don't have -- I'd want to add it

1 up to give you a precise number. I wouldn't
2 want to be precise right now.

3 Q. Okay. So for my client, Actavis,
4 what percentage of the promotion do you assign
5 to my client?

6 A. So I didn't -- as I said, I don't
7 want to give a percentage. I think that at the
8 peak, you had 50 sales reps, if my numbers are
9 right. I'd want to check. Others, I think --
10 you know, again, I'd want to -- I haven't given
11 a precise number, but I think that can give you
12 a sense of -- sense of the scope of --

13 Q. So I'm not really interested in
14 just a commentary as to what you learned about
15 what we did.

16 I really want to know the
17 methodology that you used to determine the
18 amount of promotion per defendant. So what
19 process did you go through to make your
20 determinations about that?

21 A. I don't think the report gives you
22 an exact quantitative aspect. It doesn't
23 allocate responsibility between those
24 defendants.

1 If you'd like, I'd be happy to
2 give -- if you define "responsibility" for me,
3 I'd be happy to give you my opinion, but I
4 didn't give a precise quantitative aspect.

5 Q. So what I really want is the
6 opinions you're going to give at trial. At
7 some other time, we can talk about your other
8 opinions, because I do find that interesting,
9 too. But I'm interested in the opinions that
10 you plan to give at trial.

11 Do you plan to give at trial
12 opinions quantifying the amount of promotion
13 done by any particular defendant?

14 A. To the extent that that information
15 is in my report and in my schedules, I'm happy
16 to testify. There are dollar numbers and sales
17 numbers and promotional numbers that are
18 identified in my report, and I'd be happy to
19 give you opinions based on those facts, right.
20 But I'm not going to -- I don't intend to go
21 outside of the report.

22 Q. So the things that would matter to
23 you in determining the impact of a particular
24 drug company's promotion, some of the things

1 that you would consider would be the number of
2 representatives. That matters to you, doesn't
3 it?

4 A. Sure.

5 Q. And it matters to you the type of
6 interaction that the representatives were
7 having with prescribers. That would be
8 relevant to your opinion, right?

9 A. Well --

10 Q. The content of what was being said.

11 A. Well said.

12 I mean, it's -- I mean, as you see,
13 the report talks about the corporate messaging.
14 It doesn't rely on just the numbers, but it's
15 the corporate messaging.

16 I mean, again, the range of
17 activities in promotion, I can probably -- in
18 one of these charts, you'll see, you know,
19 probably a list of 16, 17 highly sophisticated
20 methods to influence doctors -- KOLs, KOL
21 mapping, E-detailing, KOL channels -- each one
22 measured, each one having -- looking for the
23 return. So that there's not just one factor
24 that goes into it.

1 That's why the report tries to look
2 at the -- I mean, the range of promotional
3 activities. It's not just this individual
4 detail.

5 Q. It matters also when in time the
6 promotional activity occurred. That's also
7 relevant to your views, isn't it?

8 A. Yes, I think -- I think that's
9 fair.

10 I think we talked earlier about the
11 initial sort of -- the initial promotion by
12 Purdue, the -- what was -- you see what was
13 going on with Kadian in the late '90s, early
14 2000s with Purdue, and then you certainly see
15 other companies jumping in, trying to compete
16 and expand the market after that time period.

17 So I do think there are different
18 stages of this, so I do think timing is
19 important.

20 Q. You've a couple times in this
21 deposition talked about a shift in prescribing
22 practices, and earlier in your deposition, you
23 said, at some time after the 1980s, there was a
24 shift in prescribing practices.

1 Can you be more specific about when
2 that shift occurred?

3 A. Yeah. Well, I can give you time
4 points.

5 Q. Sure.

6 A. Okay? So if you look at the --
7 sort of the state of medical practice, okay, on
8 oxy --

9 Q. For the record, can you put a
10 sticker on that book that you're looking at,
11 please?

12 A. Do I get it back?

13 Q. Yeah, just -- and we can say for
14 the record the pages that you're referring to
15 so we don't have to copy the whole book.

16 A. So, I mean, this is --

17 Q. What page number are you referring
18 to?

19 (Exhibit Kessler-42 marked for
20 identification and attached to the
21 transcript.)

22 (Reporter interruption.)

23 MS. LEVY: I'm sorry.

24 BY MS. LEVY:

1 Q. That is Exhibit 43 [sic]. It is
2 marking a book in front of Dr. Kessler that is
3 entitled what, sir?

4 A. 1980 Drugs of Choice 1981. I guess
5 between 1980 and 1981.

6 It's -- actually, the title page is
7 Drugs of Choice 1980-1981, Walter -- Dr. Walter
8 Modell.

9 Q. So my question to you is, when --
10 when, just an answer in years -- did the shift
11 in prescribing practices that you've described
12 in your deposition -- when did that occur?

13 A. So, I mean, I think that the shift,
14 as this book talks about -- it says that, We
15 find that the risk of addiction greater than
16 that -- and it's talking about oxycodone, for
17 example -- We find the risk of addiction
18 greater than that attributed to morphine...

19 And it ends up, Oxycodone is best
20 considered as an orally-active morphine and
21 should not be dispensed as freely as if it were
22 a codeine.

23 And it concludes, Oxycodone,
24 although useful, cannot be recommended as a

1 drug of choice.

2 And so I think that was generally
3 the practice in the 1980s, and I think -- I
4 think in these documents and in market share,
5 you can see the very -- the rise in the number
6 of prescriptions over time, both with OxyContin
7 and Duragesic and that that increase, which is
8 pretty dramatic -- I guess between 1998 and
9 1999 is where it starts, and you can see it
10 for, I mean, other trends.

11 So you have to plot the trend data,
12 but I think that this sort of long-acting
13 opioids or, certainly, the extended-release
14 opioids, you see that there is -- I guess from
15 1998 to 2004 -- and this is not a full year,
16 but you see this -- the market increased.

17 So I think the fact is, I'm going
18 even earlier, 1980s. I mean, this stuff was
19 not viewed as drugs of choice, more addictive
20 than morphine.

21 And then this continues to take
22 off, and you -- I have charts elsewhere that go
23 even further. And as our share of voice
24 increases, as this promotion increases, these

1 drugs -- Opana ER does as well, for example.

2 So what you see is just graphic,
3 but I think the answer is the -- that sort of
4 tipping point, probably around '99, 2001, but
5 continued to grow.

6 Q. So let me see if I can do this from
7 across the table, and if I can't, I may come
8 sit beside you.

9 But I want the record to be clear
10 about what you're looking at, so let's mark for
11 the record another one of your --

12 A. It's already marked.

13 MR. RAFFERTY: It's already marked.

14 MS. LEVY: Oh.

15 Q. Kessler Number 33, which has the
16 marking that you put on it, Market Share, this
17 is your market share pile? Is that a fair way
18 to call it? This is your market share module?
19 How do you -- how do you refer to it?

20 A. There's some market share. There's
21 other market share in the report and the
22 reliance list, but these are just some of the
23 cut-and-paste. I don't want to represent these
24 are the only ones. There are many documents

1 cited in the report.

2 Q. I would like to give Exhibit 33 a
3 name, so what do you want to call it?

4 A. Let's call it market share.

5 Q. Okay. So --

6 A. Market share papers.

7 Q. Your market share papers, as
8 reflected in Exhibit 33 --

9 I believe when you gave your
10 testimony -- I'm going to turn, if you don't
11 mind, to a chart that I want to ask you some
12 questions about.

13 MS. LEVY: So I want to put a
14 sticker on -- another sticker -- I'll
15 call it Exhibit Kessler-43, which I
16 would like to also mark for -- just this
17 page.

18 (Exhibit Kessler-43 marked for
19 identification and attached to the
20 transcript.)

21 BY MS. LEVY:

22 Q. This says -- 2003 Total Market,
23 12.12 Billion, is the title of the graph.

24 Are you with me?

1 A. Yes. Actually, I think it's
2 probably -- the graph is probably U.S. Pain
3 Market, title. But this -- you can call the
4 title anything you want.

5 Q. The single page we're referring to
6 as "2003," I just want to understand the
7 testimony that you gave a minute ago about
8 this. This charts 1998 through what point in
9 time? 2004?

10 A. 2004 is not a complete year.
11 That's an expected year, I believe.

12 Q. Okay. And is this an illustration
13 of the shift in prescribing that we were
14 talking about?

15 A. It certainly is a shift in the
16 increase. So you start with the red, which is
17 long-acting opioids, I mean, as a -- as a
18 group, right. So you have \$783 million in '98
19 growing, in the red, to \$3.5 billion.

20 And you also have some increase in
21 short-acting opioids, going from about 970 to
22 double.

23 So you have -- on the one hand, you
24 have about a five-fold increase in long-acting

1 opioids and a doubling in short-acting opioids.

2 Now, I just want to -- there are
3 other graphs that I have over extended periods
4 of time, but we picked out -- I mean, you asked
5 me for a question, and I think this does
6 correspond to some of the growth.

7 But, I mean, to be fair, we
8 probably should have in front of us and pull up
9 the growth over several decades. And I think
10 you would see where -- where there was sort of
11 a tipping point, where the growth started to
12 accelerate. So it's that greater acceleration.

13 Q. What is the dip in 2004?

14 A. That's just not a full year. So
15 if you --

16 Q. I see.

17 A. If you had a full year --

18 Q. It's a partial year?

19 A. It's a partial year. So that's
20 why -- if you did a full year, I can assure
21 you, it would be -- the growth is substantial.

22 Q. Has the shift in prescribing --
23 well, when you talk about -- when you said
24 earlier in the deposition -- I wrote down these

1 words -- "shift in prescribing" -- those were
2 the three words I wrote down -- shift from what
3 to what?

4 A. Well, I mean, you can -- you can do
5 that, I mean, just in total number of scripts,
6 right, for the opioid class. I mean -- or even
7 the pain -- I think for the opioid class.
8 Let's stay with that. And I think you can look
9 at the increase in either total -- total
10 prescriptions, total sales volume.

11 I think that was the -- that growth
12 and that acceleration of that growth from
13 basically -- you know, we can get the numbers
14 from the 1980s, but I think this reflects the
15 fact that if it's not a drug of choice,
16 right --

17 I mean, there was -- there were a
18 combination, and there may have been an IR
19 product. Put a question mark around that.

20 But you would look at -- the sales
21 volume was relatively small, and then there was
22 a continued growth in increasing the number of
23 prescriptions. That's what I mean by a "change
24 in medical practice," how doctors actually

1 prescribe.

2 Q. In your view, is all of the
3 increased growth due to drug company misconduct
4 or only part of the increased growth? Is it
5 all of it that can be attributable to bad
6 conduct or just a part of the increased growth?

7 A. Let me think about the answer to
8 that question.

9 Q. I really just want a succinct
10 answer. I don't want to know why you think
11 that; I just want to know if all of the growth
12 or part of the growth is due to misconduct.

13 A. I think the growth is due to the
14 marketing and promotion. I would never -- I
15 think it would be foolhardy to say all the
16 growth in every instance. I wouldn't want to
17 testify to that.

18 But this growth happened because of
19 marketing and promotion. And that change in
20 prescribing, it was due to the perception of
21 opioids and the campaign to change prescribing.

22 Q. Did the -- did the growth at some
23 point start to recede?

24 A. Yes.

1 Q. When? Not a long commentary, just
2 when?

3 A. I would need the graphs into the
4 teen years, and it would depend by manufacturer
5 and by generic. So it's a little complicated.

6 My sense is -- I mean, I'd want to
7 have the graphs in front of me before --
8 certainly for certain manufacturers, it
9 receded. There were changes that were made,
10 and -- but I'd want the data in front of me
11 before I'd give you an opinion on that
12 question.

13 Q. So my question was, Did the growth
14 at some point start to recede? Your answer
15 was, Yes.

16 Then I asked you just to tell me
17 when. Is your answer to that, I don't know?

18 MR. RAFFERTY: Object to the form.

19 A. I can't be precise here, in part,
20 because --

21 Q. Is your answer, I don't know?

22 A. No, no. Well --

23 Q. I know you don't like to say that.
24 I just want to know if you -- do you know, or

1 don't you know? Answer that.

2 MR. RAFFERTY: That's not -- that's
3 not the only two options.

4 Answer the question as best you
5 can, or tell her you can't answer it.

6 A. So we have to be a little more
7 precise in just -- we're talking about the
8 growth of what? The pain market? The
9 long-acting opioid market? The short-acting
10 opioid market? The opioid market? I mean, all
11 those are different questions.

12 OxyContin, Kadian, those are all --
13 would be -- have different answers, and we
14 really would need -- I need the data in front
15 of me to thoughtfully and accurately answer
16 those questions.

17 Q. Let's talk about Kadian. When did
18 the Kadian market recede?

19 A. You get more than everyone else,
20 right?

21 Q. Let me see if you can answer my
22 question.

23 A. Sure. Sorry.

24 Q. When did the market for Kadian

1 recede? What year?

2 A. So let me just look at my --

3 Q. And the answer is either a year or
4 you don't know the answer to the question.

5 MR. RAFFERTY: No.

6 Or you need to look at something in
7 order to get the answer.

8 MS. LEVY: Right. I don't want --

9 MR. RAFFERTY: There is a lot of
10 different answers.

11 MS. LEVY: I want a succinct answer
12 to this question.

13 MR. RAFFERTY: But you don't get to
14 dictate what that answer is.

15 MS. LEVY: Sure don't. But I do
16 get to dictate that it's succinct.

17 MR. RAFFERTY: No, you don't.
18 That's what the judge is for, the
19 special master. You don't get to rule.

20 MS. LEVY: Indeed.

21 A. I don't have the graph -- I don't
22 have the graph in front of me. I have data of
23 what its market share was in 2011 and 2016. I
24 have representations. And those are very

1 small, and there was a -- there was a decrease
2 from 2011 to 2016.

3 Q. So as you sit here right now with
4 what you have in front of you, when did the
5 market for Kadian recede?

6 I just want a -- I just want -- and
7 if you don't know, you can say the words "I
8 don't know."

9 MR. RAFFERTY: Object to the form.

10 A. I don't have the graph -- I don't
11 have the graph --

12 Q. Okay.

13 A. Hold on a second. Is that true?

14 So if you look, for example, in
15 Summit County, I think you see a receding
16 around 2012 to 20- -- 2012, 2014.

17 If you look at Cuyahoga, you see,
18 again, there's a receding between 2011 and
19 2012.

20 You see that in Cleveland, and you
21 see that in Akron, and you see that in Ohio,
22 generally. So I think -- I think -- I think it
23 would be fair to say --

24 I don't -- the data I'm looking at

1 as of right now is only between 2009 and 2017,
2 so don't hold me to years before. I would want
3 to see that data.

4 But I think it would be fair to
5 say, if there were an inflection point in a
6 rate of acceleration, it would be 2012.

7 Q. I'm sorry. I didn't understand
8 that answer.

9 In 2012, did the market for Kadian
10 increase or decrease?

11 A. It decreased. It you -- you asked
12 for the rate of -- rate of deceleration.

13 Q. I didn't ask for any rates.

14 I just asked, did the market
15 increase or decrease?

16 A. You said -- you said, when did it
17 decline?

18 Q. Mm-hmm. A year. What year?

19 MR. RAFFERTY: Objection. He's
20 answered the question.

21 A. So if you want to look at -- I can
22 give you specifically -- we can -- we can put
23 it up.

24 You know, in Ohio -- let's just

1 take Ohio -- it was 20 -- 2009, it was 27,000.
2 2010, it was 25,000. In 2011, it was 26,000.
3 It was relative- -- those numbers are
4 relatively consistent.

5 In 2012, it was 5,792. 2013,
6 2,692. 2014, 1,063. 2015, 556. 2016, 450.
7 2017, 365.

8 I can give you those numbers
9 nationally. I can give you Summit. I can give
10 you Akron. So -- you have this document.

11 Q. Let's stick that on --

12 A. Sure.

13 Q. -- 44.

14 So for the record -- so the record
15 is clear, the numbers that Dr. Kessler was
16 reading is coming from the page that we're
17 going to now mark as Exhibit 44.

18 (Exhibit Kessler-44 marked for
19 identification and attached to the
20 transcript.)

21 BY MS. LEVY:

22 Q. And when you were reading those
23 numbers, I assume, Doctor, you're referring to
24 numbers of prescriptions?

1 A. So this is --

2 Q. Just is it the number of
3 prescriptions or something different?

4 A. Let me -- let me just read the
5 caption so I can be accurate. It is the total
6 number of Kadian prescriptions that I just gave
7 you.

8 Q. So is it your view that Kadian
9 should be taken off the market? Yes or no?

10 MR. RAFFERTY: If you can answer it
11 that way.

12 A. I've given no such opinion.

13 Q. I didn't ask you if you've given an
14 opinion.

15 I'm asking you if it is your
16 opinion, as you sit here today, that Kadian
17 should be taken off the market, or, No, I don't
18 think Kadian should be taken off the market.

19 MR. RAFFERTY: Or you can't answer
20 the question as she has stated it yes or
21 no.

22 A. I've not -- I've not given an
23 opinion on that, ma'am, so I would have to
24 think about that.

1 I have no -- no opinion on that.

2 My guess is, you know -- my guess is, after I
3 thought about it, I would probably come out and
4 say I'm not opposed to products being on the
5 market if their marketing is well-controlled.

6 Q. Kadian came on the market during
7 the Kessler administration; is that correct?

8 A. Came on in 1996.

9 Q. Kadian came on the market during
10 the Kessler administration; is that correct?

11 A. Yes.

12 Q. Now, the FDA -- Kadian came on the
13 market pursuant to the FDA's normal approval
14 process for pharmaceuticals, right?

15 A. I wasn't involved in Kadian. I
16 know it was approved in July of '96. I have no
17 reason to believe there was -- there was
18 anything that was -- that was different with
19 regard to that approval process.

20 Q. Kadian's NDA application was
21 accompanied by clinical studies, correct?

22 A. Let me -- I'd have to review --

23 Q. Do you know if Kadian's NDA
24 included clinical studies? Do you know?

1 A. Yes.

2 Q. Did it include clinical studies?

3 Yes or no?

4 A. I have to go back and look. My
5 memory is fading at the moment. If you'll give
6 me a couple of minutes, I can tell you exactly.
7 I'd have to refresh my memory of what those
8 clinical studies were, because I'm just fading
9 at the moment. But I'm happy to -- if you give
10 me two minutes, I can double-check that.

11 Q. Did you read the clinical
12 studies -- have you at any point in time read
13 the clinical studies that accompanied the
14 Kadian NDA?

15 A. I'm sure I -- I'm sure I looked at
16 the basis for the approval at some point, but
17 right now, I'm a little vague, and I'd have to
18 review that.

19 Q. As you sit here right now, before
20 looking at anything, you don't remember
21 anything about those studies, do you?

22 MR. RAFFERTY: Object to the form.

23 A. I'm fading on those studies, to be
24 honest. I don't -- I don't have a recollection

1 of those studies. I'd have to refresh my
2 memory.

3 Q. Okay. Do you have any reason to
4 believe that the -- that CDER, under your
5 administration, didn't do its job when it
6 reviewed the Kadian NDA? Do you have any
7 reason to believe it didn't do what it was
8 supposed to do?

9 A. No.

10 Q. And you've said -- you've said
11 before that you have a great deal of confidence
12 in the FDA, right?

13 A. I said a lot of things about the
14 FDA.

15 MR. RAFFERTY: Object to the form.

16 A. I'm not sure if I've used exactly
17 those words. I mean, if you have a quote and
18 wanted to give it to me --

19 Q. Well --

20 A. I've said a lot of things about the
21 FDA.

22 Q. Let's not worry about what you've
23 said in the past.

24 As you sit here today, tell me if

1 those statements are true or false.

2 The FDA is the most important
3 consumer protection agency in the world. True
4 for false?

5 A. If you don't care what I've said in
6 the past, why quote me? You're quoting me.

7 In the past, I have said that.

8 Q. Okay. I'm going to see if you can
9 answer this question that I'm asking you. This
10 is going to be really easy for you.

11 MR. RAFFERTY: Object to the
12 commentary.

13 Q. This is true or false? The FDA is
14 the most important consumer protection agency
15 in the world. Is that true or false?

16 MR. RAFFERTY: Object to the time
17 frame.

18 Q. I don't want to know what you've
19 said in the past, what you think you've said in
20 the past, what you might have said in the past.

21 I want to know, as you sit here
22 today, do you agree that the FDA is the most
23 important consumer protection agency in the
24 world?

1 MR. RAFFERTY: Object to the form.

2 A. I would agree with that.

3 Q. Okay. You always have and continue
4 to have every reason to trust the judgment of
5 officials of the FDA; is that correct?

6 MR. RAFFERTY: Object to the form.

7 A. I wouldn't -- sitting here today, I
8 wouldn't say it like that.

9 Q. Okay.

10 A. I said I have enormous respect for
11 the people who work at the agency, but like any
12 other organization that has 10,000 people,
13 there are people whose judgment I would trust
14 with my life, and there are -- like any
15 organization, there are clunkers.

16 And so I would not make a blanket
17 statement across the board. I have enormous
18 respect.

19 Q. Janet Woodcock, the head of CDER,
20 you would put her in the category of someone
21 you have enormous respect for?

22 A. I appointed Janet.

23 Q. That's not the question I asked.

24 Do you have enormous respect for

1 Janet Woodcock?

2 A. Respect? Sure. I appointed her.
3 I picked her out. She was a, you know,
4 three-level medical reviewer, and I made her
5 the head of the center ten years ahead of when
6 she was supposed to be. I have enormous
7 respect.

8 Do I agree -- I have enormous
9 respect for her contribution to service, to her
10 integrity. Has she made mistakes? Absolutely.
11 Do I disagree with her? Absolutely. Have we
12 had conversations like that? Absolutely.

13 I defended Janet Woodcock, I mean,
14 you know, pretty vigorously because I thought
15 people at the agency should get defended in
16 certain circumstances.

17 Q. What about Carl Peck? Would you
18 say the same about him?

19 A. Carl Peck, you have to love. Carl
20 Peck -- I would trust Carl Peck with
21 pharmacokinetics because he sees
22 pharmacokinetics in everything. And I think he
23 contributed and we worked mightily together.

24 Do I agree with him on everything?

1 Absolutely not. Do I think every question can
2 be answered by a PK analysis? Absolutely not.
3 Did he make a mistake on pilot drug, et cetera?
4 We could spend hours talking. But I love Carl
5 Peck, and enormous respect for Janet.

6 Q. The FDA has the highest safety and
7 efficacy studies in the world, right?

8 A. Studies in the world, no. FDA
9 doesn't do studies. The manufacturers does the
10 studies. So I'm not sure what that -- the
11 question means.

12 Q. The doctors and scientists at FDA
13 are as smart and talented as any you've ever
14 seen; is that right, sir?

15 MR. RAFFERTY: Object to the form.

16 A. That's exactly the kind of
17 statement that I made earlier. If you're
18 asking me, there are those who are very
19 talented, and there are those who are clunkers,
20 and there are those who could earn umpteen
21 dollars times their salary on the outside and
22 are pure gold, and there are others who make
23 mistakes. And even those who you trust
24 sometimes make mistakes. And we all do that.

1 Q. Do you agree that the United States
2 food and drug laws have the highest safety and
3 efficacy standards in the world?

4 MR. RAFFERTY: Object to the form.

5 A. I did at a point in time.

6 Q. Do you agree now, as you sit here
7 today?

8 A. I think in certain areas, we may be
9 being usurped by certain of the European -- in
10 certain areas. I think that was probably true
11 at a point in time, but I have some concerns in
12 certain areas.

13 Q. If a company gets a warning letter
14 and the company wanted to be a model citizen,
15 one thing it would do -- the first thing it
16 would do is immediately stop using the
17 offending promotional materials. That's one
18 thing you would want to see a company that got
19 a warning letter do, correct?

20 A. Sure. But I think there would be
21 something you'd want to do first.

22 Q. Another thing you would want a
23 company to do when it gets a warning letter
24 from the FDA about promotional materials is to

1 work with the FDA to formulate a corrective
2 action plan, right?

3 A. Sure. But I would think there
4 would be something even more important.

5 Q. What first? What would one want to
6 do first?

7 A. You'd want to look and see not just
8 what this promotional material was or what your
9 corrective action plan, you would want to
10 understand the corporate strategy or the
11 corporate culture that contributed to that
12 warning letter, and you would want to make sure
13 you would change that corporate culture or that
14 corporate strategy rather than just discarding
15 X piece of paper or coming up with a plan.
16 That's what I think it is more important when
17 you got a warning letter.

18 Q. So if you're advising a company as
19 to how to be a model citizen and do the right
20 thing when you get a warning letter, you need
21 to figure out why the statement got in and
22 correct that as a matter of corporate conduct?
23 Is that what you're saying?

24 A. Sure. But you'd have to ask

1 yourself -- there's a term -- and I'm not a big
2 fan of it, the term. It's a little bit of a
3 slogan, but it's a culture of compliance. And
4 is there anything in that culture of compliance
5 that is off, that begat that warning letter.

6 Q. You'd also want to work with the
7 FDA and create a corrective action plan that
8 was effective, correct? Yes or no?

9 A. Sure, yes.

10 Q. And you are aware that Actavis got
11 a warning letter with respect to Kadian.
12 That's something that you talk about in your
13 report, right?

14 A. 2010, I believe, yes.

15 Q. And, in fact, Actavis did
16 immediately stop using the materials. You're
17 aware of that?

18 A. I am.

19 Q. And Actavis also worked with the
20 FDA to create a corrective action plan,
21 correct?

22 A. Correct.

23 Q. And you are aware that the FDA
24 agreed with and said it appreciated the

1 corrective action plan, correct? Are you aware
2 of that?

3 A. I'm not sure the word
4 "appreciated," but I'll take your stipulation
5 to that. I don't recall, but I'll -- I'm sure
6 the FDA said something akin to that.

7 Q. And part of the corrective action
8 plan was to send Dear Healthcare Professional
9 letters to every physician who had received the
10 projects materials.

11 Are you aware of that?

12 A. Correct.

13 Q. In addition, part of the corrective
14 action plan was to send additional letters out
15 to consumers, correct?

16 A. Correct.

17 Q. Okay. And you don't have any
18 reason to believe that the FDA was dissatisfied
19 with that corrective action plan, do you?

20 A. Correct.

21 Q. Okay. There was no enforcement
22 action or any further action taken on Kadian by
23 the FDA at any point in time after that,
24 correct?

1 A. Correct. And we see the decrease
2 in numbers and eventually the decrease in
3 promotion, et cetera, that followed shortly,
4 and we see this inflection point in Kadian's
5 sales.

6 Q. Do you believe that Actavis did the
7 right thing when it got its warning letter?

8 A. I have no reason to doubt that.

9 Q. Okay. There's another document
10 that you cited in your report in paragraph 520
11 that you take issue with for Actavis.

12 A. If I can find my report.

13 Q. Your report is buried in my pile,
14 too. Let's look together.

15 A. 520?

16 Q. I think that's correct. Let me
17 turn to it.

18 MS. LEVY: There's a request for a
19 break. Let's go off the record.

20 THE WITNESS: I think 520 raises
21 some questions.

22 MS. LEVY: Hang on a second.

23 Let's go off the record.

24 VIDEO OPERATOR: 4:40 p.m., we're

1 off the video record.

2 (Recess from 4:40 p.m. until
3 4:53 p.m.)

4 VIDEO OPERATOR: 4:53, we're on the
5 video record.

6 BY MS. LEVY:

7 Q. Doctor, you once referred to the
8 FDA processes as being the gold standard for
9 drug approval.

10 Do you still have that opinion
11 today?

12 A. I think so.

13 Q. How many opioids were approved in
14 the Kessler administration?

15 A. I don't know -- I mean, the ones
16 obvious -- there were approved -- let me just
17 do it in my head. Duragesic was approved
18 before me.

19 There were two. There was Kadian,
20 and as far as brand name drugs, Kadian and
21 Duragesic -- I'm sorry -- Kadian and Oxy were
22 done during that seven-year period. I'd have
23 to look and see how many on the generic side.

24 Q. Do you know the number of

1 opioids -- just do you know the number of
2 opioids that were approved during the Kessler
3 administration?

4 A. I can tell you NDAs.

5 Q. How many? Number only.

6 A. I believe there were two NDAs.

7 Q. How many ANDAs?

8 A. I don't have that number.

9 Q. You don't know?

10 A. I don't know.

11 Q. The FDA continues to approve opioid
12 products on an ongoing basis, correct? Let
13 me -- I worded that poorly.

14 The FDA continues to approve new
15 opioid products on an ongoing basis, continuing
16 through today, right?

17 MR. RAFFERTY: Object to the form.

18 A. There's an issue with regard to
19 that in my conversations with the Commissioner,
20 but the way the statute is written, there's
21 some discussion of whether that needs to be
22 changed.

23 Q. Not my question.

24 The FDA continues to approve

1 opioids, this year has even approved opioids,
2 correct?

3 A. This year, it would be fair. But
4 when you say "continued," you're implying into
5 the future, and I'm just saying there is an
6 issue about that.

7 Q. Okay. The FDA approved new opioids
8 in 2015, '16, '17, '18 and '19, correct?

9 A. And some to great criticism.

10 Q. No doubt that the FDA has been
11 criticized widely by some folks for doing so.

12 But it continues to approve these
13 products, correct?

14 A. Including me.

15 MR. RAFFERTY: Object to the form.

16 Q. And there have been a number of
17 citizens' petitions and other requests to the
18 FDA to make changes and to make -- to take
19 certain actions with respect to opioids on the
20 market.

21 You're aware of those, right?

22 MR. RAFFERTY: Objection.

23 A. We've discussed those in the past
24 two days.

1 Q. And you disagree with the FDA's
2 opinions and outcomes in responding to those
3 petitions? You disagree with the FDA in that,
4 right?

5 MR. RAFFERTY: Object to the form.

6 A. I don't think that's a fair
7 statement. That's not my testimony. If you
8 want to show me a specific sentence in FDA, I
9 can tell you what I would agree with and what I
10 disagree. I won't make a blanket statement --

11 Q. That's fair.

12 A. -- that I agree or I disagree.

13 Q. And I believe we established this
14 earlier in the record, but just in case.

15 You are not giving testimony or
16 speaking for the FDA, correct?

17 A. That's correct.

18 Q. You haven't been employed by the
19 food -- by the Health and Human Services
20 Department since the -- 21 years; is that
21 right?

22 A. You can do the math at this hour.
23 But I would certainly -- it's very important,
24 underscore it, put an asterisk, put an

1 exclamation point. I'm in no official
2 capacity. Sometimes I get put on television
3 because they're not -- sometimes I get put on
4 television because the agency is not speaking.
5 But I have no official capacity.

6 Q. Okay. There are plenty of things
7 that you disagree with the FDA on, right?

8 A. Things I agree with them and things
9 I disagree with them.

10 Q. Okay. Now, the -- one of the
11 things you believe is that Kadian should not be
12 prescribed for chronic pain, right? Or is that
13 an overstatement?

14 A. So I think if you did that, if you
15 just left it that way, I think that would be
16 inaccurate.

17 Q. Okay. Do you have any -- strike
18 that.

19 Kadian was approved by the FDA in
20 1996 for use in patients with chronic moderate
21 to severe pain who require repeated dosing with
22 a potent opioid analgesic, correct?

23 A. I thought it said continuous,
24 around-the-clock. Do you want to just give

1 me -- maybe I'm misreading.

2 Q. Let me -- let me read you --

3 A. Just give me the indication. I can
4 pull it. Let me pull it.

5 Q. I just want to ask -- I'm asking --
6 we're going to do that in a minute, but listen
7 to this specific question, and I would like to
8 know if you agree or disagree.

9 A. Okay. I'm just pulling the label
10 so I can be exact. But go ahead. I'm
11 listening, ma'am. I don't want to delay.

12 Q. No. Take your time. Do what you
13 need to do. Put the label in front of you.

14 And for the record, are you looking
15 at your report?

16 A. Just looking at the schedules that
17 have the labels, and I'm looking specifically
18 for Kadian and multiple changes, and let's just
19 look at the indications section -- I'm just
20 trying to get the indications section --
21 interactions with alcohol -- go ahead. Just
22 read me the indications section, or read me
23 whatever you want.

24 Q. So no, that's not my question,

1 actually. I want to wait until you can pay
2 attention to the question I'm going to ask you.

3 A. Sure. And I apologize. I'm just
4 trying to pull the labeling.

5 Q. Would you like to see the Kadian
6 current label?

7 A. I'd love to see it in 1996. That's
8 what I -- and I apologize --

9 Q. I'm going to give you just another
10 minute, and then I'm going to move on with my
11 question.

12 A. Keep going on, please.

13 Q. Okay. I'm going to say a
14 statement, and I want to know if you agree.
15 And here is the statement: Kadian was approved
16 by the FDA in 1996 for use in patients with
17 chronic moderate to severe pain who require
18 repeated dosing with a potent opioid analgesic.

19 That's true, right?

20 A. No, I'd want to see the label
21 before I'd answer that question.

22 (Exhibit Kessler-45 marked for
23 identification and attached to the
24 transcript.)

1 BY MS. LEVY:

2 Q. Let's mark -- let me hand you what
3 I've marked as Kessler Exhibit 45.

4 A. Thank you very much, ma'am.

5 Q. Okay. And this is a document dated
6 July 11th, 1997. You see in the top right-hand
7 corner?

8 THE WITNESS: Can I ask someone
9 just get me the Kadian label, the
10 approved label, please? Yeah, thank
11 you.

12 A. I see this.

13 Q. Okay. And you recognize the
14 letterhead on this document as FDA Center For
15 Drug Evaluation and Research. You recognize
16 that letterhead?

17 A. I know that letterhead.

18 Q. And the Center For Drug Evaluation
19 and Research is often referred to as CDER,
20 right?

21 A. Correct.

22 Q. CDER's understanding on July 11th,
23 1997 was that Kadian was approved by the FDA in
24 1996 for use in patients with chronic, moderate

1 to severe pain that require repeated dosing
2 with a potent opioid analgesic.

3 Do you agree with that?

4 A. You've got to show me the label and
5 I can answer that question.

6 Q. Okay. In --

7 A. This is a medical officer's review.
8 We don't know whether that's shorthand. We
9 don't know at what point in time.

10 Just somebody show me the label.
11 This shouldn't be a hard question to answer.
12 The answer to your question is exactly what it
13 says in the approved label.

14 And I'm sorry, I just can't pull it
15 up at this moment in time.

16 Q. Is it okay to prescribe Kadian to
17 patients with chronic pain?

18 MR. RAFFERTY: Object to the form.

19 A. Can I see the label and I'll be --
20 I'm not going to answer --

21 Q. You can't answer that without
22 seeing the label?

23 A. I want to see the label, yes. I
24 want to see the label.

1 Q. Without seeing the label, can you
2 answer this question: Is it okay to prescribe
3 Kadian to patients with chronic pain?

4 A. Again, either show me the label or
5 I can't answer the question. I don't want to
6 guess. My understanding is that there was
7 around-the-clock, extended, continuous, and
8 those things are in the label.

9 But I don't have -- my memory is
10 fading and I'm just -- the courtesy of please
11 show me the label and I can answer that
12 question, or I can't answer the question.

13 Q. Let me point you back to Exhibit
14 45. You'll certainly agree with me that CDER
15 believed that Kadian was approved for patients
16 with chronic pain. That was CDER's statement,
17 right?

18 MR. RAFFERTY: Object to the form.

19 Q. Yes or no? Did you hear my
20 question, Dr. Kessler?

21 A. I heard your question.

22 Q. Okay. What was my question?

23 A. Your question -- let me point you
24 to Exhibit 45; you'll certainly agree with me

1 that CDER believed that Kadian was approved for
2 patients with chronic pain. That was CDER's
3 statement.

4 The label I have is Kadian capsules
5 approved for use in the introduction is an
6 extended-release oral formulation of morphine
7 indicated for the management to moderate or
8 severe pain when a continuous, around-the-clock
9 analgesic is needed for an extended period of
10 time.

11 That's what I remember. So if we
12 can -- and that's from an FDA document. But
13 let's -- if someone gets me the label, I can --
14 we can be exact. I mean, I would think --

15 Q. Keep going.

16 A. I would think after I spoke on
17 Duragesic, I mean, and an extended release
18 morphine several years later, that some of that
19 would be --

20 Q. You see what I've highlighted in
21 Exhibit 45?

22 A. Yes.

23 Q. Is CDER correct or incorrect, or
24 you don't know? Which is it?

1 A. If this does not correspond to the
2 label, this is incorrect.

3 Q. And you don't know whether it does
4 or doesn't?

5 MR. RAFFERTY: Object to the form.
6 Let the record reflect counsel refuses
7 to show him the label.

8 A. Okay. I have to be precise here.
9 If you can show me the label and what it's
10 approved for in 1996, I can be exact. That's
11 my only request.

12 (Exhibit Kessler-46 marked for
13 identification and attached to the
14 transcript.)

15 BY MS. LEVY:

16 Q. So I'm going to show you what's
17 marked as Exhibit 46.

18 A. Thank you so much.

19 Q. And I'm going to give you -- I'm
20 going to ask you to take a look at that
21 document and tell me -- the question is this.
22 Do you --

23 A. Can we just establish the date of
24 this, kindly?

1 Q. Look on the front page, bottom
2 left. It's the current Kadian label.

3 A. Correct.

4 Q. My question to you is: Do you have
5 any problems with this label?

6 MR. RAFFERTY: Object to the form,
7 overly broad.

8 Q. Yes or no? That's all I want to
9 know.

10 A. Yes.

11 Q. Okay. This label is no good, in
12 your view?

13 MR. RAFFERTY: Object to the form.

14 A. I didn't say that. I just said --
15 you asked me if I have problems with that. The
16 problem is, this talks about a drug being
17 indicated for long-term opioid treatment and
18 extended release treatment.

19 Again, there's good parts of this
20 label, around the clock, and for which
21 alternative treatment options are inadequate.

22 The problem is, is it didn't
23 disclose that there's not adequate and
24 well-controlled trials that support that

1 indication.

2 So this is -- in that case, you
3 would want to -- I mean, if I were Commissioner
4 at the time, I would say, we can make that
5 statement, right. I mean, I would probably
6 want to emphasize cancer as I did in '94, maybe
7 in a rare small incidence beyond that, but I
8 would want to put in this that there was not
9 adequate and well-controlled clinical trials to
10 support this, but we're doing it anyway.

11 Q. Okay. So the Kessler that's here
12 for litigation believes that the label is not
13 supported by adequate and well-controlled
14 trials. Is that a fair statement?

15 MR. RAFFERTY: Objection to the
16 characterization.

17 Q. Yes or no?

18 A. So Dr. Gottlieb, Dr. Califf,
19 Dr. Woodcock all believe -- all have stated,
20 right, that there is not adequate and
21 well-controlled clinical trials to support
22 long-term use for opioids. That is not a
23 litigation position. If you look --

24 Q. That's your opinion in this

1 litigation, right?

2 A. Well --

3 Q. That is your opinion today in this
4 litigation?

5 MR. RAFFERTY: Objection.

6 Don't interrupt him. If you're
7 going to characterize something as
8 "litigation Kessler," then he has a
9 right to respond to it.

10 Q. And is it your opinion --

11 A. Can I --

12 Q. -- that this label --

13 A. I need to finish my answer.

14 Q. -- just yes or no, is your label --

15 A. I need to finish my answer.

16 Q. Okay. Go ahead.

17 MR. RAFFERTY: You don't have to
18 answer anything yes or no just because
19 she tells you to.

20 A. I'm trying to -- I would like to --

21 Q. I'd like for you to give me a
22 succinct answer. Is that label flawed?

23 A. Yes, that label is -- but please,
24 this is so important, okay. The randomized

1 adequately controlled trial that we have, the
2 space trial, there's only one, shows no
3 efficacy benefit from long-term opioids.
4 That's the one we have. There are others that
5 are in the works.

6 Making an indication without
7 adequate and well-controlled clinical trials by
8 definition is flawed.

9 Sometimes you do flawed things when
10 you're in a corner, right. Things -- there's
11 been a practice in place for 20 years. You
12 just don't want to hurt anyone. You want to
13 leave the door open beyond cancer pain, right.
14 Because when you're at FDA, right, you realize
15 that somebody may, because of your action, jump
16 out of a window if you deprive them -- and you
17 lose sleep on that, right, so you're very
18 careful on what you do.

19 But that is a flawed statement
20 because it is contrary to the adequate and
21 well-controlled scientific evidence. That is
22 not a litigation position. That is the fact.

23 Q. Okay. So can you fix it for me,
24 please. Take that pen that I just put in front

1 of you and fix that label.

2 MR. RAFFERTY: Objection. He
3 doesn't have to do that.

4 Q. Yeah. Can you do that?

5 MR. RAFFERTY: No, he doesn't. He
6 doesn't have to draw anything.

7 A. I can give you certain
8 recommendations. I mean, I have no opinion on
9 that. But I would give you certain elements --

10 Q. Now, you either can or can't.
11 That's what I want to know. Are you able to
12 take --

13 A. I can give you --

14 Q. Just a minute. It's a yes or no
15 question. Can you do this: Can you take that
16 pen and just fix the Kadian label? Is that a
17 thing you could do?

18 A. I could do that if you want to
19 spend the next maybe hour and my thinking about
20 it, and I can give you the elements -- I
21 probably couldn't give it to you as artfully
22 done, but let me give you the elements that I
23 think have to be in this label.

24 Q. I just wanted to know if it's

1 something that can be done. So you disagree
2 that this is an appropriate label. You
3 disagree that this label is not appropriate?

4 A. I don't think --

5 Q. It is not appropriate --

6 MR. RAFFERTY: Objection to the --
7 quit cutting the witness off.

8 MS. LEVY: Stop talking over me.

9 MR. RAFFERTY: No, I'm not --

10 MS. LEVY: You have plenty of time
11 to object.

12 MR. RAFFERTY: No.

13 Q. In your view, Dr. Kessler, this
14 label is flawed. That's your testimony?

15 MR. RAFFERTY: Object --

16 Q. Simple as that, right?

17 MR. RAFFERTY: Object to the form.

18 A. I think what I testified to a
19 couple of minutes ago is, there were some good
20 aspects of this label, right, but there was
21 still need for improvement in this label that
22 reflects the current -- the science of this and
23 could more appropriately further protect the
24 public health.

1 Q. You don't think -- do you think
2 opioids are appropriate to use for long-term
3 pain? Do you think that, as you sit here
4 today?

5 MR. RAFFERTY: Object to the form.

6 Q. Are they appropriate? I'm not
7 asking about anything else other than your
8 opinion as to whether they're appropriate.

9 MR. RAFFERTY: Object to the form.

10 Q. Yes or no?

11 MR. RAFFERTY: Object to the form.

12 And you don't have to answer yes or
13 no.

14 A. I think a physician in his or her
15 judgment, recognizing that there is not
16 adequate and well-controlled trials to support
17 that decision for safety and effectiveness,
18 after -- in either cancer pain -- in certain
19 types of cancer pain or in some rare instances
20 of non-cancer pain, maybe as third line, maybe
21 as fourth line, but I would use them sparingly
22 in light of the fact that there is not adequate
23 and well-controlled clinical trials.

24 But if your back's against the

1 wall, you know, we all do what we have to do.

2 Q. Have you ever taken opioids?

3 MR. RAFFERTY: Objection.

4 Do not answer that question.

5 That is wholly inappropriate, and
6 you know it.

7 Q. You've prescribed opioids
8 certainly, right? I think you told us that
9 yesterday.

10 MR. RAFFERTY: Mark that part of
11 the transcript for me, please.

12 Q. Have you?

13 A. Yes. I --

14 MR. RAFFERTY: That is an abusive
15 question.

16 A. I have either prescribed morphine
17 in the oncology wards. I may have prescribed
18 certain combination products, not for its pain
19 effect, but for its antitussive effect, for its
20 central nervous effect in certain neurological
21 antitussive episodes.

22 But I think -- I mean, I do it, you
23 know, I probably -- you can count on a hand or
24 two hands the number of times I've written in

1 my career -- I've been a hospitalist, so maybe,
2 you know, the service may have prescribed when
3 I'm the attending, but I -- it's very
4 occasional.

5 Q. And I think we established this
6 earlier in your testimony. You were a
7 pediatrician; is that right?

8 A. Still am a pediatrician.

9 Q. And you are not an oncologist, are
10 you?

11 A. I did a lot of oncology. I spent
12 an enormous amount of time because I was the
13 attending --

14 Q. Are you an oncologist?

15 A. No, I'm not, but I do a lot of --
16 when you're the hospitalist on the adolescent
17 floor, the floor is filled with --

18 Q. Sure. That wasn't my question.

19 A. But I did --

20 Q. Are you an oncologist?

21 A. No, but I've done a lot of
22 pediatric oncology.

23 Q. Sure. And you told us yesterday on
24 the area of your expertise that you took a

1 marketing class. You don't have a degree in
2 marketing, do you? Do you have a degree? It's
3 a very easy question.

4 A. It's not an easy question.

5 Q. Okay. Do you have a degree, yes or
6 no?

7 A. Well --

8 Q. Or you can't answer it?

9 A. No, I can answer it. I mean, so I
10 did --

11 Q. Stop. If you can't answer it with
12 a yes or no --

13 A. I did -- I did --

14 Q. Can you answer it with a yes or no?

15 A. I have something called an advanced
16 professional certificate from the NYU Stern
17 School of Management. They keep on asking me
18 for donations. They think I'm a graduate, but
19 I only did deliberately the first year, the
20 basic courses in business school -- and that
21 included market --

22 Q. You don't have a degree.

23 A. I have an advanced --

24 Q. That's not a degree.

1 A. I'll let others characterize the
2 degree. Believe me, I'm trying to give away
3 degrees at this point. I have enough degrees.

4 Q. And do you have consider yourself
5 to be an expert in marketing?

6 A. I think I have -- when it comes
7 to --

8 Q. Yes or no?

9 MR. RAFFERTY: No, it's not a yes
10 or no question. It's not.

11 Q. Let's back up. Can you answer this
12 question with a yes or no?

13 A. With regard to drug marketing --

14 Q. You do think you're an expert?

15 MR. RAFFERTY: Quit cutting off the
16 witness.

17 Q. Yes or no?

18 A. Yes.

19 Q. Okay. That's all I wanted to know.
20 And I don't even want to know why.

21 All right. Let's take a look at a
22 document that I'm marking as Exhibit 47.

23 (Exhibit Kessler-47 marked for
24 identification and attached to the

1 transcript.)

2 BY MS. LEVY:

3 Q. Exhibit 47 --

4 A. Yeah.

5 Q. -- this is a document that you have
6 cited in paragraph 389.2 in your report,
7 correct?

8 A. There's three documents that I've
9 cited. I think there's a -- if you can hand me
10 the February document there's --

11 MR. WEINBERGER: Can I interrupt
12 for just a second?

13 Counsel, let me refer you to the
14 rules of the Northern District of Ohio
15 Federal Court, 30.1, Decorum: Opposing
16 counsel and the deponent must be treated
17 with civility and respect. Ordinarily
18 the deponent must be permitted to
19 complete an answer without
20 interruption --

21 MS. LEVY: Pete, you can cut this
22 out. You are now filibustering and
23 wasting time on purpose.

24 MR. WEINBERGER: Let me finish.

1 -- by counsel --

2 MS. LEVY: I'm not going to allow
3 you to waste my -- we're going to add
4 time --

5 MR. WEINBERGER: You can add time.

6 MS. LEVY: -- on this record --

7 MR. WEINBERGER: You can add time.

8 MS. LEVY: -- for as much time as
9 you take reading rules to me.

10 MR. WEINBERGER: Stop talking over
11 me. 30 seconds. I am asking you, as an
12 Officer of the Court, to follow the
13 rules and to act with civility towards
14 this witness.

15 Absent that, we will take this up
16 with the Court.

17 (Exhibit Kessler-48 marked for
18 identification and attached to the
19 transcript.)

20 BY MS. LEVY:

21 Q. I'm going to hand you what has been
22 marked as 47, and you also have --

23 A. Let's go to the paragraph number.

24 Q. 47 and 48 you have in front of you.

1 MR. RAFFERTY: I think she's
2 talking about exhibits, not the report.

3 THE WITNESS: Yeah.

4 A. But these are cited in 520, is that
5 what it is?

6 Q. 389.

7 A. 389, paragraph 520.

8 Q. Yeah. I have very limited
9 questions.

10 A. Sure.

11 Q. So I want to be clear and
12 transparent with you, Doctor.

13 A. Sure.

14 Q. I do not believe that I'm getting
15 succinct questions, so I reserve every right to
16 go to the special master and ask for extra time
17 with you.

18 I'm going to ask you really careful
19 questions and see if you can answer just what I
20 ask and nothing more. Can we try our best to
21 do that going forward?

22 A. I would love to get out of here --

23 Q. Okay. So --

24 A. -- as much as you would.

1 (Reporter interruption.)

2 Q. Okay. Let's talk about the
3 document that I just put in front of you that's
4 Exhibit 47.

5 A. Yes, ma'am.

6 Q. Okay. You cite that this
7 document -- in your report, do you cite that --
8 this document in your report, sir?

9 A. I do.

10 Q. Okay. You can see and will agree
11 with me that this is a draft document? Do
12 you -- can you see that?

13 A. I see there's handwriting on
14 this -- I see there's handwriting on this
15 document. I don't see the word "draft," but
16 feel free to point it to me.

17 Q. Okay. Let's ask a different
18 question. Do you know if this is a draft or a
19 final document?

20 A. I don't know the answer to that --
21 I don't see the word "draft" on it. I do see a
22 handwriting. And last night I noticed
23 something in this, so I may be able to
24 anticipate your question.

1 Q. Do you know if this document that
2 we are looking at together was ever used? Do
3 you know the answer to that?

4 A. I don't know.

5 Q. Okay.

6 A. I don't know the answer to this.

7 And to make life a little easier, I
8 did see last night, in pulling this, that
9 there's some handwriting changes with peaks and
10 valleys -- I mean, this does not look -- this
11 looks like a final presentation in February.
12 This has this crossed out. And my report
13 should reflect that.

14 Q. Okay. Let's pick up what's marked
15 as Exhibit 8 -- 48, I'm sorry. Do you know if
16 Exhibit 48 is a draft document or final
17 document? Do you know?

18 MS. AMINOLROAYA: Can you identify
19 the document, Counsel?

20 MS. LEVY: I'm sorry. I just
21 handed it to counsel.

22 Q. Do you know the answer to that
23 question?

24 A. I can only tell you that it is not

1 marked "draft," and companies tend not to do
2 presentations that -- where it's not -- I mean,
3 my experience is, you mark things "draft."

4 Q. So you assume that it's a final?

5 A. No. My testimony is, it's not
6 marked "draft." I see "draft" nowhere on this
7 document. I see a different version in March
8 23rd.

9 I have questions about the March
10 23rd document because I do see handwritings. I
11 don't see that same handwritings here.

12 Q. Do you know if Exhibit 48 is a
13 draft or final? Do you know that?

14 A. I know it doesn't say "draft."

15 Q. I'm going to point your attention
16 just to the Bates number on the bottom
17 left-hand corner.

18 A. We're in 48?

19 Q. In 48.

20 A. Yeah.

21 Q. That's labeled 1554. Do you see
22 that?

23 A. Yes.

24 Q. What does it say under --

1 A. 1554.

2 Q. What does it say there?

3 A. It says, insert picture of dosing
4 guide.

5 Q. Does that indicate to you, Doctor,
6 that this is a draft document and not a final?

7 A. No. It depends how it's
8 constructed. I wouldn't want to give any
9 opinion on that.

10 Q. Okay. So you don't know?

11 A. I would not give any opinion on
12 that based on that paragraph.

13 Q. Okay. And now let's look further
14 at 1527 in the same document of Exhibit 48,
15 1527. This is two pages in.

16 A. Yes.

17 Q. What does that slide say?

18 A. Pain slides, insert summary slides
19 from Marion's deck.

20 Q. Now that you've looked at that,
21 doesn't it look to you, sir, like this is a
22 draft document, not a final document?

23 A. I think it's possible. I mean, I
24 think that raises some questions.

1 Q. Okay. Now, there's a difference in
2 marketing that results in new prescriptions and
3 marketing that results in substitution of a
4 product. Do you agree with that?

5 A. Yes, and you can see that kind of
6 analysis in certain companies' documents, yes.

7 Q. Okay. Not all marketing has the
8 impact of having new patients get opioids. You
9 would agree with that, right?

10 A. Correct.

11 Q. It's a simple question.

12 A. I said --

13 THE WITNESS: Gerard, can I just
14 see General 1, please.

15 Q. Do you agree with the statement
16 that not all opioid marketing would result in
17 new patients getting opioids? Do you agree
18 with that? Simple question.

19 A. I think it would be fair to say
20 there is a time where companies are trying to
21 get market share away from something, and a --
22 can I get -- I'm sorry -- influence on doctors.

23 I think there's both. There's new
24 market share -- I mean, there's substitution,

1 and I think those things are tracked.

2 I didn't see it from Actavis. But
3 I think those things are tracked in a number of
4 documents with a good deal of specificity that
5 I have seen.

6 So for example, you can have in
7 OxyContin continuing Rx's and new to brand and
8 new starts and switches.

9 So here you have what's called new
10 starts, which would be 36.7, and switches,
11 which would be substitution, so both can go on.

12 Q. Without looking at the transcript,
13 what was my question to you?

14 MR. RAFFERTY: Objection.

15 You don't have to answer that.

16 Q. Do you remember what I asked you?

17 MR. RAFFERTY: You do not have to
18 answer that.

19 If you've got a question for the
20 witness, ask the question.

21 Q. Do you remember the question I just
22 asked?

23 A. Please, let's go on.

24 MR. RAFFERTY: It's not a memory

1 test. Read the question back to --

2 Q. So you told us yesterday another --
3 you gave us -- well, strike that.

4 One of the things -- one of the
5 things we asked you about yesterday, Doctor,
6 was your payment for your work in this case.

7 I wrote down in my notes that you
8 told us yesterday that you had made millions of
9 dollars in testifying in lawsuits. Do you
10 recall that testimony?

11 A. Two points I'm not sure I'm
12 tracking. You're asking me for my payment for
13 work in this case, and that I've made millions
14 of dollars. Those things were unrelated
15 questions.

16 Q. Okay. So I was unclear -- I was
17 unclear yesterday, so let me ask you some
18 questions to clear that up.

19 How much have you been paid for
20 your work in this case?

21 How much have you --

22 (Reporter interruption.)

23 A. I'm sorry, I apologize --

24 Q. How much have you charged for your

1 work?

2 A. (Nonverbal response.)

3 (Reporter interruption.)

4 MR. RAFFERTY: You have to say

5 "zero."

6 THE WITNESS: Zero.

7 Q. How much --

8 A. Let me just make sure I'm
9 reading -- listening to your questions -- your
10 exact questions.

11 How much have you been paid?

12 I've been paid zero in this case.

13 Q. How much have you billed for your
14 time and your work in this case?

15 A. "This case" being the MDL?

16 Q. Yes.

17 A. Zero.

18 Q. Are you working for free in the
19 MDL?

20 A. No.

21 Q. It's just you haven't submitted
22 your invoices yet?

23 A. Fair.

24 Q. So you estimated yesterday that you

1 had spent hundreds and hundreds of hours. Is
2 that correct?

3 A. Fair.

4 Q. Okay. But you can't say more
5 specifically than that?

6 A. I have not added it up.

7 Q. You have kept track of it somewhere
8 though; is that correct?

9 A. There are numbers on -- you know,
10 they're on scribbled papers, yes.

11 Q. So you could look that up and get
12 that information to us?

13 A. I'm sure at a certain point, you
14 know, those -- I'm sure when invoices get done,
15 whatever agreement you have, whatever the rules
16 are, I leave it to counsel to work out these
17 things.

18 Q. And now, going to your income for
19 testimony in litigation in total -- not just in
20 this case, all litigation -- I think that was
21 what you said you had made millions of dollars
22 doing that. Is that correct?

23 A. Over a ten-year period, correct.

24 Q. And can you be more specific than

1 that? Do you know how many millions of
2 dollars?

3 A. No.

4 Q. You haven't kept track of that?

5 A. No. You have to ask -- I don't do
6 the finances.

7 I know it's certainly millions. I
8 think that would be accurate. I don't know
9 exactly. Over a ten-year period.

10 Q. And is it over \$10 million?

11 A. I wouldn't want to hazard a guess.

12 Q. You genuinely don't know?

13 A. I genuinely don't know. I've not
14 added it up, what the total is.

15 Q. Your current billing rate is a
16 thousand dollars an hour; is that correct?

17 A. Yep.

18 MS. LEVY: All right. I'd like to
19 take a short break to figure out how to
20 use my last minutes. If we want to, we
21 can just stay right here.

22 VIDEO OPERATOR: 5:29, we are off
23 the video record.

24 (Recess from 5:29 p.m. until

1 5:54 p.m.)

2 VIDEO OPERATOR: 5:54, we are on
3 the video record.

4 BY MS. LEVY:

5 Q. Thank you, Dr. Kessler. We have
6 just a few number of minutes and a lot of
7 defendants, so I appreciate your patience while
8 we try to figure out how to allocate our last
9 little bit of time.

10 The first thing I want to clear up
11 for the record is administrative with respect
12 to Exhibit 42.

13 Can you tell us for the record --
14 so we don't have to copy the whole book -- what
15 pages of Exhibit 42 that you referred to
16 earlier in this deposition?

17 A. I believe they are tabbed, ma'am,
18 and the pages include 219 and 220.

19 Q. Okay. You understand that Actavis
20 did not acquire Kadian until December of 2008?
21 You know that, right?

22 A. Correct.

23 Q. So any documents with respect to
24 Kadian prior to 2008 are not Actavis documents.

1 You understand that, right?

2 A. Are not Actavis documents? I
3 believe Alpharma owned it until 2008. So that
4 would be correct. That would be correct.

5 Q. You anticipated my next question.

6 And is it your position, sir, that
7 Alpharma is responsible for inappropriate
8 marketing with respect to Kadian?

9 MR. RAFFERTY: Object to the form.

10 A. I didn't sort out -- don't take the
11 manufacturer too seriously. I don't mean that.
12 I don't mean to diminish -- look at the drug
13 and the date. The documents may be --
14 Kadian -- even sometimes something is labeled
15 Allergan. It can be used sometimes --
16 sometimes certain manufacturers appropriate
17 certain sales promotional materials when they
18 acquire -- it's complicated.

19 So just look at the drug and the
20 documents and whoever the manufacturer is -- is
21 at the time of the document that I have
22 referenced is what I mean in the report. I'm
23 drawing no legal conclusion about if I buy a
24 company, do I buy what I'm responsible for. I

1 leave that to other -- to the lawyers and
2 others to sort out. I'm not sorting out
3 relative responsibilities when a company
4 acquires another -- when a company acquires a
5 drug.

6 Q. You're planning to offer an opinion
7 that the marketing of Kadian had some impact on
8 the opioid crisis, right?

9 A. Yes. I mean, and use the evidence
10 there regardless of the manufacturer.

11 And again, I'm just referring to
12 this as a general rule in the report because
13 there is a number, for example, of Cephalon we
14 saw being acquired by Teva. So they may be
15 Cephalon; they may be Teva; they may be
16 Teva/Cephalon. Just focus on the drug.

17 Q. You made no effort to sort out what
18 part of the marketing problems were
19 attributable to Actavis versus Alpharma, did
20 you?

21 MR. RAFFERTY: Object to the form.

22 A. Correct.

23 Q. Okay. Thank you.

24 And so on a relative basis, you

1 don't believe that the problems you saw with
2 the marketing of Kadian on a relative basis
3 were that big of a problem, honestly, do you?

4 MR. RAFFERTY: Object to the form.

5 A. I think when -- I think there are
6 other promotional campaigns that had a much
7 greater impact than Kadian's.

8 Q. One of the things that I was left
9 scratching my head on -- well, place-hold that.

10 You understand that the FDA tracks
11 prescription data, right?

12 A. FDA buys data that tracks
13 prescription data.

14 Q. You're exactly right.

15 You understand that FDA purchases
16 data in order to be able to track
17 prescriptions, right?

18 A. Correct.

19 Q. And it does, in fact, use the data
20 that it purchases for that purpose? You know
21 that?

22 MR. RAFFERTY: Object to the form.

23 A. It can for different purposes.

24 Q. And the FDA, from the Kessler

1 administration all the way to today, has taken
2 some actions and made changes with respect to
3 its views on opioids? Is that a fair statement
4 in general?

5 A. Correct.

6 Q. Is there any action taken by the
7 FDA, any specific action, that you believe it
8 took that it couldn't have taken earlier?

9 MR. RAFFERTY: Object to the form.

10 A. I don't understand the question.
11 Sorry.

12 Q. The institution of the REMS
13 protocols, FDA could have done that earlier,
14 right?

15 A. It did risk maps earlier. The 2007
16 statute gave it specific authority -- the FDA
17 2007 gave the FDA authority, for example, to
18 order safety studies. Only recent legislation,
19 the Cures Act, gave FDA authority to require
20 efficacy data to compel it once a drug is on
21 the market.

22 Q. Couldn't have done it any earlier,
23 in your view? Could not have?

24 MR. RAFFERTY: Object to the form.

1 A. It's a legal question --

2 Q. You don't know?

3 MR. RAFFERTY: Object to the form
4 and the interruption of the witness
5 again.

6 Q. Do you know?

7 MR. RAFFERTY: Which question do
8 you want him to ask [sic]?

9 Q. I want to ask if he knows if the
10 FDA -- just a yes or no, if you know. I don't
11 want to know what it is. I just want to know,
12 does Dr. David Kessler --

13 A. I can answer your question.

14 Q. -- know the answer to this
15 question?

16 A. Yes.

17 MR. RAFFERTY: And if he can give
18 the answer.

19 Q. Could the FDA -- does Dr. David
20 Kessler know this? Could the FDA have acted
21 earlier? Does he know the answer?

22 MR. RAFFERTY: Object to the form.

23 A. I'm requiring on the long-term
24 efficacy study, not a safety study. I can tell

1 you that FDA's position, in talking to
2 Dr. Gottlieb and in the Cures Act was that FDA
3 required congressional statutory authority.

4 Q. So it could not have acted earlier?

5 A. That was FDA's position of late in
6 talking to the Commissioner of what he stated.

7 Q. Could the FDA have requested label
8 changes or changes in indications to various
9 opioids a long time ago, if it wanted to?

10 MR. RAFFERTY: Object to the form.

11 Q. Could have done that, right?

12 A. Certainly it could have. It can
13 always request, correct.

14 Q. And another thing that left me
15 scratching my head is -- because I'm going to
16 wonder this -- is it true that you do not know
17 how much money you made last year?

18 MR. RAFFERTY: Object to the form,
19 asked and answered.

20 A. I do not know how much money I
21 made. I can tell you my wife does the
22 finances.

23 Q. Do you have to sign your tax
24 return?

1 A. For last year?

2 Q. 2018.

3 A. Yes, I filed. I signed the form
4 that asked for an extension. I've seen no tax
5 returns.

6 Q. What about 2017?

7 MR. RAFFERTY: I'm going to object.
8 And quite frankly --

9 MS. LEVY: You're welcome to
10 object.

11 MR. RAFFERTY: -- this is getting
12 harassing, and if it continues, we're
13 going to just instruct him not to
14 answer.

15 MS. LEVY: You're welcome to do
16 that.

17 MR. RAFFERTY: He's not going to
18 talk about how much money he makes --

19 Q. Dr. Kessler --

20 MR. RAFFERTY: -- overall because
21 that's not relevant under Rule 26, as
22 counsel well knows.

23 Q. What are your sources of income
24 aside from the income that you're getting from

1 testifying?

2 MR. RAFFERTY: Objection.

3 Q. What other sources of income do you
4 have?

5 MR. RAFFERTY: You don't have to
6 answer that question, Doctor.

7 A. I'm happy to answer that question,
8 unless counsel instructs me otherwise.

9 Q. What are they?

10 A. I'm happy to.

11 I have a number of different
12 sources of income. I have book royalties and
13 book contracts. I told you about private
14 equity. I have academic salary. I have
15 consulting.

16 Q. And you truly don't have any idea
17 how much money you make annually?

18 MR. RAFFERTY: It's done. The last
19 question was asked.

20 Q. You have no idea?

21 MR. RAFFERTY: You don't have to
22 answer any more questions, Doctor.

23 MS. LEVY: Are you instructing the
24 witness not to answer that question?

1 MR. RAFFERTY: I am, because it's
2 been harassing.

3 MS. LEVY: Okay.

4 VIDEO OPERATOR: 6:03, we are off
5 the video record.

6 MS. LEVY: Hang on. We're not
7 going off the record.

8 We are leaving this transcript open
9 both so the witness can answer this
10 question; in addition, I have a great
11 number of questions still for this
12 witness. Other counsel in this room
13 also have additional questions.

14 We are going to request -- reserve
15 every right to request additional time
16 with you, Dr. Kessler. So we may be
17 seeing you again.

18 Anybody else have anything else
19 you'd like to put on the record?

20 MR. RAFFERTY: Yes. That is that
21 we gave -- Dr. Kessler gave 14 hours per
22 the instructions, was cooperative,
23 answered all of the questions, many of
24 which were irrelevant, harassing, and

1 quite frankly, ethically questionable
2 about his own medical care. And so
3 y'all do whatever you want.

4 And the other thing is, these will
5 go with the court reporter, and the
6 originals will come back to Dr. Kessler.
7 Any originals that are being copied will
8 come back to Dr. Kessler.

9 MS. LEVY: Hang on. Everybody in
10 turn.

11 MS. FREIWALD: I don't care whether
12 I do it or somebody else does it. But
13 by my count, there were 11 of these
14 large spreadsheet files. Somebody can
15 confirm if that's correct or not. Some
16 were marked General.

17 And please, Dr. Kessler, if you
18 think I'm mischaracterizing it, just say
19 because I'm trying to create a record
20 here.

21 Some are more general; some were
22 specific to different clients. I saw --
23 give me one second here.

24 It looked to me like there were a

1 couple that were Janssen. One was
2 called super poppy; one Purdue; MNK;
3 Actiq; Payments to Parties. And then
4 there was another set that were Market
5 Share, Influencing Doctors, General 1
6 and 2.

7 And we're going to ask the court
8 reporter to put an exhibit sticker on
9 each one of those following after
10 whatever our last exhibit number is.

11 COURT REPORTER: These have already
12 been marked.

13 MS. FREIWALD: Okay. So the court
14 reporter will keep track of them by
15 number, and she'll make the copies and
16 then get the originals back to
17 Dr. Kessler. That's fine.

18 COURT REPORTER: Anything else for
19 the record?

20 MR. RAFFERTY: Nothing from the
21 plaintiffs.

22 THE WITNESS: Thank you, sir, very
23 much.

24 Thank you, ma'am.

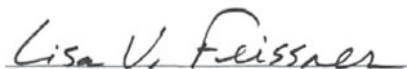
1 VIDEO OPERATOR: 6:06 p.m., we are
2 off the video record.

3 (Off the record at 6:06 p.m.)
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C E R T I F I C A T E

I, Lisa V. Feissner, RDR, CRR, CLR,
Notary Public, certify that the foregoing is a
true and accurate transcript of the deposition
of said witness, who was first duly sworn by me
on the date and place hereinbefore set forth.

I further certify that I am neither
attorney nor counsel for, nor related to or
employed by, any of the parties to the action
in which this deposition was taken, and
further, that I am not a relative or employee
of any attorney or counsel employed in this
action, nor am I financially interested in this
case.



Lisa V. Feissner, RDR, CRR, CLR

Notary Public

Dated: April 30, 2019

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1 WITNESS NAME: DAVID A. KESSLER, M.D.

DEPOSITION DATE: APRIL 26, 2019

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3 ERRATA

4 PAGE LINE CHANGE REASON

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1 ACKNOWLEDGMENT OF DEPONENT

2

3 I hereby acknowledge that I have read
4 the foregoing deposition, pages 420 - 809,
5 dated April 26, 2019, and that the same is a
6 true and correct transcription of the answers
7 given by me to the questions propounded, except
8 for the changes, if any, noted on the attached
9 Errata.

10

11

12 SIGNATURE:

DAVID A. KESSLER, M.D.

13

14 DATE:

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18 WITNESSED BY:

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20 DATE:

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